Immediate Display DDM
Display Date 4-1-08 3:47 pm
Publication Date 4-21-08
Certifier R. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0189] (formerly Docket No. 2003N–0312)

Meeting to Present Changes to the Animal Feed Safety System Project and the Ranking of Feed Hazards According to the Risks They Pose to Animal and Public Health; Part 3: Swine Feed Example; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: "Meeting to Present Changes to the Animal Feed Safety System (AFSS) Project and the Ranking of Feed Hazards According to the Risks They Pose to Animal and Public Health; Part 3: Swine Feed Example." We are holding the public 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. The following topics will be discussed: The third draft of the AFSS Framework and work-in-progress on a method for ranking animal feed contaminants by their risks to animal and human health. Elsewhere in this issue of the **Federal Register**, FDA is announcing a related public meeting notice.

Date and Time: The public meeting will be held on May 14, 2008, from 9 a.m. to 4:30 p.m.

Location: The public meeting will be held at the Gaithersburg Holiday Inn, 2 Montgomery Village Ave., Gaithersburg, MD 20877. There is parking adjacent to the building. The building is also accessible by public transportation. (Take

Metro Red Line to Shady Grove Station and board Ride-On bus 124 to Frederick Rd. at Perry Pkwy. Then, cross the roadway and walk approximately 1½ blocks north to building entrance.)

Contact Person: For general information: 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 Web site, go to *http://www.fda.gov/cvm/AFSS.htm#Meetings.* Due to limited meeting space, registration will be required. We strongly encourage early registration.

Additionally, please notify Nanette Milton if you need any special accommodations (such as wheelchair access or a sign language interpreter) at least 7 days in advance of the meeting.

Comments: Regardless of attendance at the public meeting, interested persons may submit written or electronic 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.regulations.gov.* Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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. The docket will remain open for written or electronic comments for 30 days following the meeting.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*

SUPPLEMENTARY INFORMATION:

I. Background

AFSS is FDA's program for animal feed aimed at protecting human and animal health by ensuring animal feed is safe. AFSS covers the entire spectrum of agency activities from preapproval of food additives 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. It includes oversight of all feed ingredients and mixed feeds at all stages of manufacture, production, distribution, and use, whether at commercial or non-commercial establishments. Further, AFSS includes feed intended for food-producing and non-food-producing (companion) animals.

During the past several years, FDA has been considering needed changes to AFSS to ensure it is comprehensive, preventive, and risk-based. As part of this effort, the agency released its AFSS Framework document in February 2005 and discussed it at a public meeting held in April 2005 in Omaha, NE. Subsequently, a revised Framework document was made available to the public in December 2006. The revised Framework document includes, among

other things, changes necessitated by FDA's Amendments Act of 2007 (FDAAA), which was signed into law September 28, 2007. The ranking scheme for estimating risks posed by feed contaminants to animal and human health consists of two components, namely health consequence scoring and exposure scoring, which were covered at previous meetings in 2006 and 2007, respectively. At this meeting, the agency will describe the model it has developed to rank the risks of the more common hazards in swine feed. The Framework document identifies numerous projects including the development of a model for ranking the 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 comparative 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 during feed manufacturing, storage, distribution, or transportation 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 four public meetings to discuss AFSS. The first two meetings, held in September 2003 and April 2005, focused on obtaining input on what was lacking and where and how to address identified deficiencies in the agency's feed safety program. At the next two meetings, held in September 2006 and May 2007, the agency covered developmental aspects of the AFSS risk-ranking model. To determine the comparative 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). During the 2006 and 2007 meetings, we described the methods used by the agency to develop scoring systems for ranking animal and human health consequences arising from feed hazards and for ranking exposure to those feed hazards, respectively. The public meetings included active participation by consumers, animal feed processors, animal producers, and State and other Federal Government agencies. Both before and following the meetings, we placed a number of documents in FDA's docket (found in brackets in the heading of this document) for the AFSS project. These documents included transcripts of the meetings, summaries of breakout 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 listing 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 May 14, 2008.

As a result, in part, of recent actions by the Congress and the Administration, a third draft of the AFSS Framework will be presented at the public meeting. We will also discuss in more detail, where appropriate, several of the gaps identified in the Framework document. In addition, we will show how health consequence scoring is combined with exposure scoring to rank the risks of contaminants in animal feed. Swine feed will be used as the example. We also plan to briefly present the risk-based method being developed to rank feed inspectional programs.

II. Public Meeting

We are holding the public 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 "Draft AFSS Framework, 3rd Edition" and "Risk-Ranking of Feed Hazards: Swine Feed Example." The Framework document will summarize the agency's current efforts to modernize its animal feed safety program. The Risk-Ranking document will provide the methods for ranking potential biological and chemical hazards in feed, using swine feed as an example. 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.

An additional public meeting sponsored by the Center for Veterinary Medicine (CVM) will be held on May 13, 2008, at the same site as the AFSS public meeting. The purpose of the CVM meeting will be for the agency to receive comments on the pet food safety section of FDAAA (Public Law 110–85). Information on the CVM public meeting will be publishing elsewhere in this issue of the **Federal Register**.

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division

of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: 4/15/08
April 15, 2008.

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08–????? Filed ??–??–08; 8:45 am]

BILLING CODE 4160–01–S

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL
Dawn P. Hawkins