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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

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Certifier D. Hawkins

Docket No. FDA-2007-N-0442 (formerly Docket No. 2007N-0487)

Opportunity for Public Input on Standards for Pet Food and Other Animal Feeds; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to obtain input from stakeholder groups, including, but not limited to, the Association of American Feed Control Officials (AAFCO), veterinary medical associations, animal health organizations, and pet food manufacturers, concerning the development of ingredient standards and definitions, processing standards, and labeling standards for pet food. These standards were mandated by the FDA Amendments Act of 2007 (FDAAA). We also would like to obtain input on whether the ingredient standards and definitions and processing standards should cover all animal feeds. 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 13, 2008, from 8 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 the Metro Red Line to Shady Grove Station, then take Ride-On bus 124 to

Frederick Rd. at Perry Pkwy., then cross the roadway and walk approximately 1 ½ blocks north to the building entrance.)

Contact Persons: For general information, Tracey Forfa, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-9000, FAX: 240-276-9030, e-mail: Tracey.Forfa@fda.hhs.gov; or for information on registration, Nanette Milton, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-453-6840, FAX: 240-453-6880, e-mail: Nanette.Milton@fda.hhs.gov.

Registration: We request that you preregister to ensure there is sufficient room. Additionally, to assist us in scheduling, we ask that you notify us through the preregistration process if you wish to make a public comment at the meeting. To preregister, please send an electronic mail message to Nanette.Milton@fda.hhs.gov no later than May 7, 2008. Your e-mail should include the following information: Your name, company or association name and address as applicable, phone number, and e-mail address. Please state whether you are speaking on behalf of an organization or as an individual. You will receive a confirmation within 2 business days.

FDA also will accept walk-in registration at the meeting site, but space is limited. FDA will try to accommodate all persons who wish to make a public comment at the meeting, including those who register at the meeting site; however, the time allotted for public comments may depend on the number of persons who wish to speak.

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

A notice in the **Federal Register** about last minute modifications that impact a previously announced public meeting cannot always be published quickly enough to provide timely notice. Accordingly, you should check the FDA Web site at <http://www.fda.gov/cvm> to learn about possible modifications before coming to the meeting.

Comments: To ensure consideration of your comments regarding the development of standards for pet food, you should submit comments by June 13, 2008. While interested persons may comment orally at the public meeting, comments may also be submitted in writing or electronically in lieu of or in addition to oral comments. Send written comment submissions 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>. Follow the instructions for submitting comments.

All 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 may also view received comments at <http://www.regulations.gov>.

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

SUPPLEMENTARY INFORMATION:

I. Background

FDAAA was signed into law by the President on September 27, 2007 (Public Law 110-85). FDAAA Section 1002(a) directs that within 2 years, FDA

must establish pet food ingredient standards and definitions, processing standards, and updated standards for pet food labeling that include nutritional and ingredient information. This same provision of the law also directs that, in developing these new standards, FDA obtain input from its stakeholders, including, but not limited to, AAFCO, veterinary medical associations, animal health organizations, and pet food manufacturers. This public meeting is an opportunity for interested stakeholders to present such input and for FDA to hear directly from the public.

In the **Federal Register** of January 7, 2008 (73 FR 1225), FDA announced its intention to hold a public meeting concerning FDAAA Section 1002(a) to gather input from the interested stakeholders and other members of the public. This announcement includes further details regarding the date and location of the public meeting, and also provides additional information regarding the topics and questions to be considered. After the meeting, FDA will review all of the comments made at the meeting and those submitted in writing through the mail or electronically to Docket No. FDA-2007-N-0442 (formerly Docket No. 2007N-0487).

FDA is sponsoring an additional public meeting as part of its Animal Feed Safety System (AFSS) initiative on May 14, 2008, at the same location as the May 13, 2008, FDAAA public meeting. The AFSS is a system that FDA is developing to minimize the risk to animals and public health through the use of risk-based, preventive, and comprehensive animal feed control measures. The purpose of the additional meeting will be for the agency to present the third draft of the AFSS Framework and work-in-progress on a method for ranking animal feed hazards by their risks to animal and human health.

The revised Framework document includes, among other things, recognition of FDA's Food Protection Plan, which was announced in November 2007, and changes to the document necessitated by FDAAA. The ranking scheme for estimating risks posed by feed hazards to animal and human health consists of two components, health consequence scoring and exposure scoring, which were previously presented. At the May 14, 2008, public meeting, FDA will describe methods for ranking risks associated with biological and chemical hazards in feed, using swine feed examples.

Background material relating to AFSS, including previous drafts of the AFSS Framework document, is available at <http://www.fda.gov/cvm/AFSS.htm>.

II. Topics and Questions for Consideration at the May 13, 2008, Public Meeting:

FDA seeks input from stakeholders and other members of the public on the topics and questions discussed below. Given that time will be limited at the public meeting, FDA encourages all interested persons to submit their comments in writing to Docket No. FDA-2007-N-0442 to ensure that their comments are considered.

A. Scope of Meeting.

In enacting FDAAA Section 1002(a), Congress specifically directed FDA to establish, in consultation with relevant stakeholders and other members of the public, ingredient standards and definitions, processing standards, and updated labeling standards for pet food. FDA seeks input from stakeholders and other members of the public on the development of such standards for pet food, including on the specific questions listed below.

In addition, because pet food is well-integrated into the overall animal foods and feeds industry, FDA is concerned that certain new requirements,

if limited to pet food only, would be impractical to implement, difficult to enforce, and would not effectively provide the safety enhancements intended by FDAAA. Furthermore, because the standards mandated by FDAAA do not currently exist for any animal food or feed, limiting new requirements to pet food only would fail to address the broader food safety concerns associated with food intended for other animal species, particularly food-producing animals.

FDA is interested in obtaining input from interested stakeholders and the public as to whether the ingredient standards and definitions and processing standards should be developed for all animal feeds. There appears to be little or no difference between ingredients intended for use in pet foods and those intended for use in other animal foods and feeds. Therefore, the agency believes the most appropriate course of action is to develop ingredient standards and definitions and processing standards for all animal feeds, including pet food. FDA believes that such an approach would more effectively carry out the safety objectives of FDAAA, and the broader human food safety provisions of the Federal Food, Drug, and Cosmetic Act. The agency also seeks comment on this or other alternative approaches for implementing Section 1002(a) of FDAAA.

B. Pet Food Labeling.

1. How could the nutritional information (e.g., guaranteed analysis, nutritional adequacy statements/life-stage claims) already present on pet food labels be improved?
2. How could the ingredient information already present on pet food labels (i.e., the ingredient list) be improved?

3. How could the current feeding instructions/recommendations section already present on pet food labels be improved?

4. Should feeding recommendations be required on the labels for all types of pet food?

5. Should a Nutrition Facts box, similar to the format that appears on human food labels, replace the current Guaranteed Analysis that currently appears on pet food labels? If so, how could this Nutrition Facts box be made to clearly distinguish it from human food labeling?

6. What other information should be required on pet food labels that is not generally present on pet food products sold in the United States?

7. Are there existing state laws, regulations, guidelines, or other models that FDA should consider when drafting the proposed pet food labeling?

C: Pet Food Ingredient Standards and Definitions.

1. What kind of ingredient definitions would provide adequate information to ensure the safe and suitable use of the ingredients in pet foods? Should ingredient definitions also be developed for other animal feeds in addition to pet food?

2. Should formal standards be a part of ingredient definitions? If so, what information should be considered to establish a standard? Should such standards be developed for ingredients intended for other animal feeds in addition to pet food?

D. Pet Food Processing Standards

The AFSS initiative is intended to cover 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. Some basic elements of an animal feed safety system are described at:

<http://www.fda.gov/ohrms/dockets/98fr/03n-0312-bkg0002.pdf>

Would standards based on a risk-based, preventive, and comprehensive feed control measures approach, such as the approach described as an element of FDA's AFSS initiative, adequately address the processing standards requirement of section 1002(a) of FDAAA? If so, what aspects of procurement, processing and distribution should be included in such an approach? Should such standards be developed and applied to all animal feeds rather than be limited to pet food?

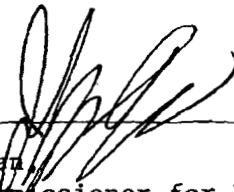
III. Other Information for the Public Meeting

FDA has posted additional information for the May 13, 2008, public meeting on the CVM Web site at *<http://www.fda.gov/cvm>*. The agency may make additional background material available to the public and will post that information on the CVM Web site as well. Additionally, background material relating to AFSS, including previous drafts of the AFSS Framework document, is available at *<http://www.fda.gov/cvm/AFSS.htm>*.

IV. Transcripts

FDA will prepare a meeting transcript that will be entered into the docket. FDA anticipates that transcripts will be available approximately 30 business days after the meeting. The transcript will also be available for public examination at the Division of Dockets Management (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

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



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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