SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product VAPRISOL (conivaptan hydrochloride). VAPRISOL is indicated for treatment of euvolemic hyponatremia in hospitalized patients. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for VAPRISOL (U.S. Patent No. 5,723,606) from Astellas Pharma, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 5, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VAPRISOL represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for VAPRISOL is 2,796 days. Of this time, 2,096 days occurred during the testing phase of the regulatory review period, while 700 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: May 6, 1998. FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on May 6, 1998.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: January 30, 2004. FDA has verified the applicant's claim that the new drug application (NDA) for VAPRISOL (NDA 21–697) was initially submitted on January 30, 2004.

3. *The date the application was approved*: December 29, 2005. FDA has verified the applicant's claim that NDA 21–697 was approved on December 29, 2005.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,745 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by May 29, 2007. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 25, 2007. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, 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. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 12, 2007.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E7–5737 Filed 3–28–07; 8:45 am]

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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 2: Exposure Scoring for Feed Contaminants; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing the following public meeting: ''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 2: Exposure Scoring for Feed Contaminants.'' The topic to be discussed will 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 a meeting held in September 2006, the agency presented its current thinking on health consequence scoring. At this public meeting, the agency will describe the methods it plans to use to develop animal and human exposure scoring for chemical, physical, and microbiological feed contaminants. At a subsequent public meeting, FDA will present information on its relative risk-ranking model and how the health consequence scoring and exposure scoring will be combined to determine the relative risks of contaminants in feed.

Date and Time: The public meeting will be held on May 22, 2007, from 9 a.m. to 4 p.m.

Location: The public meeting will be held at the Holiday Inn, 2 Mongomery Village Ave., Gaithersburg, MD 20879.

Contact: *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, or e-mail: *zoe.gill@fda.hhs.gov*.

For registration: 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, or e-mail: *nanette.milton@fda.hhs.gov*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person (see *Contact*). To obtain the registration form via the Web site, go to *http://www.fda.gov/cvm/AFSS052007PM.htm*. Due to limited meeting space, registration will be required. We strongly encourage early registration.

If you need special accommodations due to a disability, please contact Nanette Milton (see *Contact*) no later than May 15, 2007.

Comments: Written comments should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Electronic comments may be submitted to the docket at the following Web site: *http://www.fda.gov/dockets/ecomments*. Submit a single copy of electronic comments or two paper copies of any written 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 through June 21, 2007, 30 days following the meeting.

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, conducting inspections, and taking enforcement actions for ensuring compliance with agency regulations. The 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 the 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 from 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 the 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 three public meetings to discuss the AFSS. The first two meetings were held on September 23 and 24, 2003, in Herndon, VA and on April 5 and 6, 2005, in Omaha, NE. These 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 (see docket number 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 FDA's docket a number of other documents relating to the AFSS, including a framework for the AFSS that lists the principal components of the AFSS and the gaps the agency has identified which are being addressed by the agency team working on the AFSS project. These documents provided general background material on the AFSS for the third public meeting that was held on September 12, 2006, in Rockville, MD.

The September 2006 meeting was 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. In this model, information about the health consequences posed by the hazardous contaminants will be combined with information about exposures to the contaminants in animal feed. At the September 2006 meeting, the agency presented its current thinking on the development of a health consequences scoring system to represent the animal and human health consequences associated with the feed contaminants. The meeting also afforded the opportunity for attendees and agency presenters to have an open discussion concerning the health consequences approach being considered by the agency. The presentations and the transcript of the meeting have been added to the AFSS docket.

At the May 22, 2007, meeting, which will be held in Gaithersburg, MD, FDA will continue its discussions on the development of the AFSS relative risk ranking model by focusing on the exposure component of the model. The exposure scoring system under development intends to address the presence of contaminants in source materials for feed ingredients and those factors in manufacturing and/or processing that may affect the levels of contaminants in final feed formulations. At the May 2007 meeting, the agency will use the production of swine feed as an example exposure scenario to illustrate its approach to exposure assessment.

At one or more subsequent meetings, the agency will present information about how health consequences and exposure are combined to determine the relative risks of contaminants in animal feed and various aspects of the relative risk model developed by the agency.

II. Meeting

We are holding the public meeting in an effort to gather further information from you, our stakeholders, on changes to the AFSS that will help minimize risks to animal and human health associated with animal feed. Prior to the public meeting, FDA will place a document entitled ''Exposure Scoring for Feed Contaminants—A Swine Feed Example'' in the docket found in brackets in the heading of this notice. The document will summarize the agency's methods for determining exposures to physical, chemical, and microbiological contaminants that may be present in swine 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.

Dated: March 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–5820 Filed 2–28–07; 8:45 am]

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