TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
11.100	4,500	1	4,500	1	4,500

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
11.10	2,500	1	2,500	20	45,000
11.30	2,500	1	2,500	20	45,000
11.50	4,500	1	4,500	20	90,000
11.300	4,500	1	4,500	20	90,000
Total					270,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2298 Filed 2–4–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0312]

Animal Feed Safety System: A Comprehensive Risk-Based Safety Program for the Manufacture and Distribution of Animal Feeds; Notice of 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 a public meeting to discuss our progress on development of a comprehensive, risk-based Animal Feed Safety System (AFSS) describing how animal feeds (individual ingredients and mixed feeds) should be manufactured, distributed, and used to minimize risks to humans and animals. We are seeking comments and assistance in our consideration of this safety program to effectively minimize the hazards to public health posed by animal feed products.

Date and Time: The public meting will be held on Tuesday, April 5, 2005, from 8 a.m. to 5 p.m., and Wednesday, April 6, 2005, from 8 a.m. to 12:15 p.m. You may submit written or electronic comments at any time, but they would be most helpful if received on or before March 4, 2005.

Location: The public meeting will be held at The Crowne Plaza, 655 North 108th Ave., Omaha, NE 68154, 402–496–0850.

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. You can view comments FDA has received on the Internet at *http://www.fda.gov/ohrms/dockets/*.

Contacts:

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.gov*.

For Information About Registration: Brenda Boateng, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6850, FAX: 240–453–6882, or e-mail: *brenda.boateng@fda.gov*.

Registration: Registration forms are available on the Division of Dockets Management Web site at *http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm*. Although there is no registration fee for this meeting, registration is required. Due to limited meeting space, and to permit the agency to adequately prepare for the meeting, early registration is strongly encouraged. We are asking that registration occur by March 11, 2005. You may register by telephone, fax, or e-mail by contacting Brenda Boateng (*see Contacts*).

If you need special accommodations due to a disability, please contact Toni Wooten at 301–595–0796 or by e-mail at *toni.wooten@fda.gov* at least 7 days in advance of the meeting.

Transcripts: You may request a transcript of the meeting's general session in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857. The transcript will not include the individual breakout sessions, although their summaries will be included in the general session transcript. The transcript of the public meeting will be available after the meeting, at a cost of 10 cents per page. You may also examine the transcript of the meeting at the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday and on the CVM Web site at *http://www.fda.gov/cvm*.

SUPPLEMENTARY INFORMATION:

I. Background

We envision the AFSS as an umbrella regulatory program aimed at protecting human and animal health, It is intended to cover the labeling, production, and distribution of all feed ingredients and mixed feeds at all stages of manufacture, distribution, and use.

On September 23 and 24, 2003, we held a public meeting in Herndon, VA to discuss the AFSS. The public meeting included active participation of people

representing consumers, animal feed processors, animal producers, and State and other Federal Government agencies. Following the meeting, we placed a number of documents in the FDA Docket named at the beginning of this notice. These documents included a transcript of the meeting, summaries of breakout discussion groups, presentations of invited speakers, and a summary of the meeting. We stated our view that an AFSS should be comprehensive and risk-based, and we have since drafted definitions for these terms and placed them in this Docket. Likewise, we created and placed in the Docket a listing of elements we felt would be essential for process control under an AFSS. After reviewing comments to these items in the Docket, we drafted the following framework for the AFSS, including the four major components we see as comprising the AFSS:

- Component 1—Ingredients and the approval process.
- Component 2—Limits for animal feed contaminants.
- Component 3—Process control for the production of feed ingredients and mixed feed.
- Component 4—Regulatory oversight.

This new document has been added to our Web site and the Docket and will be discussed at the meeting. We also intend to discuss a draft risk-ranking model under development by the agency for determining the relative risks of the numerous hazards that may be present in animal feed. Your comments on our proposed framework, including Components 1 through 4, and any risk-related topics would be most appreciated. Please submit all comments by March 4, 2005.

II. Meeting

We are holding the meeting in an effort to further gather information from you, our stakeholders, on the design of an effective, comprehensive, preventive, risk-based AFSS that is intended to help minimize risks associated with animal feeds.

Resources and costs are important considerations in any such undertaking, and we are receptive to suggestions about how these can be controlled or used most effectively while focusing preventive efforts on important known and emerging health risks associated with animal feeds. We are particularly interested in your thoughts on the application of Hazard Analysis and Critical Control Point (HACCP) (mandatory or voluntary) to any or all segments of the industry, development of risk standards for contaminants, revising existing good manufacturing practices (GMPs) to make them more risk-based, development of GMP-type regulations and/or guidance for producers of feed ingredients and nonmedicated feeds, extending regulatory control to users of feed, and the role of State and first-party inspections.

On the morning of the first day of the meeting, we will summarize the aforementioned documents placed in our docket, followed by breakout sessions in the afternoon to discuss each topic. Additionally, one group will be asked to discuss the perceived benefits of the AFSS. The breakout group(s) on risk analysis and risk-ranking is likely to be of greatest interest to meeting attendees who have a scientific background. If you are interested in participating in the breakout group on risk analysis and risk-ranking, please indicate this on your registration form. We will do our best to accommodate these requests.

Discussions will be summarized in breakout group reports on the final day of the meeting. The meeting will wrap up with an open discussion and closing remarks.

III. Comments

Interested persons may submit written or electronic comments to the Division of Dockets Management (*see* **ADDRESSES**). Comments should be identified with the full title and the docket number found in brackets in the heading of this document. A copy of the received comments will be available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 28, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2210 Filed 2–4–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0466]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Guidance for Industry on Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing (VICH GL–37); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry (#160) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing'' (VICH GL–37). This guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document is intended to establish recommendations for internationally harmonized repeat-dose chronic toxicity testing.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance 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*. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Louis T. Mulligan, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6984, e-mail: *lmulliga@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development