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

among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Guidance on Repeat-Dose Chronic Toxicity Testing

In the **Federal Register** of October 23, 2003 (68 FR 60703), FDA published the notice of availability of the VICH draft guidance, giving interested persons until November 24, 2003, to submit comments. After consideration of comments received, the draft guidance was changed in response to the comments and submitted to the VICH Steering Committee. At a meeting held on May 3, 2004, the VICH Steering Committee endorsed the final guidance for industry, VICH GL–37. This VICH guidance is one of a series of guidances developed to facilitate the mutual acceptance of safety data necessary for the determination of acceptable daily intakes for veterinary drug residues in human food. This guidance was developed after consideration of the current practices for evaluating veterinary drug residues in human food in the European Union, Japan, the United States, Australia, New Zealand, and Canada. It also took account of available data from subchronic and chronic toxicity studies.

Information collection is covered under the Office of Management and Budget (OMB) control number 0910–0032.

III. Significance of Guidance

This document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than ''guideline.'' Because guidance documents are not binding, mandatory words such as ''must,'' ''shall,'' and ''will'' in the original VICH document have been substituted with ''should.'' Similarly, words such as ''require'' or ''requirement'' have been replaced by ''recommend'' or ''recommendation'' as appropriate to the context.

The VICH guidance (#160) is consistent with the agency's current thinking on the safety of residues of veterinary drugs in human foods. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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.

V. Electronic Access

Copies of the guidance document entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing'' (VICH GL–37) may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: January 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2266 Filed 2–4–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

University of Arkansas/Food and Drug Administration Food Labeling; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshops.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Regional Small Business Representative Program (SWR SBR), in collaboration with The University of Arkansas (UA), is announcing a public workshop entitled ''UA/FDA Food Labeling Workshop.'' This public workshop is intended to provide information about FDA food labeling regulations and other related subjects to the regulated industry, particularly small businesses and startups.

Date and Time: This public workshop will be held on April 5, 2005, from 8 a.m. to 5 p.m., and on April 6, 2005, from 8 a.m. to 3 p.m.

Location: The public workshop will be held at the Continuing Education Center in Fayetteville, AR, located downtown (2 East Center St.).

Contact: Steven C. Seideman, 2650 North Young Ave., Institute of Food Science & Engineering, University of Arkansas, Fayetteville, AR 72704, 479–575–4221, FAX: 479–575–2165, or e-mail: *seideman@uark.edu*.

For information on accommodation options, contact Steven C. Seideman (see *Contact*).

Registration: Registration by March 21, 2005, is encouraged. The University of Arkansas has a $75 registration fee to cover the cost of facilities, materials, speakers, and breaks. Seats are limited, please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close