such approach satisfies the requirements of the applicable statutes and regulations.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov.*

VI. Electronic Access

Persons with access to the Internet may obtain the draft revised guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: February 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–05014 Filed 3–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2003–D–0433]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Revised Guidance for Industry on ''Studies To Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach To Establish a Microbiological Acceptable Daily Intake (ADI)'' (VICH GL36(R)); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry (GFI #159) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological Acceptable Daily Intake (ADI),'' (VICH GL36(R)). 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 provide guidance for assessing the human food safety of residues from veterinary antimicrobial drugs with regard to effects on the human intestinal flora.

DATES: Submit either electronic or written comments on Agency guidances at any time.

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

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Silvia A. Pineiro, Center for Veterinary Medicine (HFV–157), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8227, *Silvia.Pineiro@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a revised guidance for industry (GFI #159) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological Acceptable Daily Intake (ADI),'' (VICH GL36(R)).

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 governments of Australia/New Zealand, one representative from 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. Revised Guidance on Microbiological ADI

In the **Federal Register** of June 3, 2011 (76 FR 32218), FDA published a notice of availability for a draft revised guidance entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI'' (VICH GL36(R)). Interested persons were given until August 2, 2011, to comment on the draft revised guidance. FDA received two comments on the draft, and those comments, as well as those received by other VICH member regulatory agencies, were considered as the guidance was finalized. No substantive changes were made in finalizing this guidance document. The revised guidance announced in this document finalizes the draft revised guidance dated June 2, 2011. The final revised guidance is a product of the Microbiological ADI Expert Working Group of the VICH.

This document provides guidance for assessing the human food safety of

residues from veterinary antimicrobial drugs with regard to effects on the human intestinal flora. The objectives of this guidance are to: (1) Outline the steps in determining the need for establishing a microbiological acceptable daily intake (ADI); (2) recommend test systems and methods for determining no-observable adverse effect concentrations (NOAECs) and no-observable adverse effect levels (NOAELs) for the endpoints of health concern; and (3) recommend a procedure to derive a microbiological ADI. It is recognized that different tests may be useful. The experience gained with the recommended tests may result in future modifications to this guidance and its recommendations.

III. Significance of Guidance

This guidance, 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.'' In addition, guidance documents must not include mandatory language such as ''shall,'' ''must,'' ''require,'' or ''requirement,'' unless FDA is using these words to describe a statutory or regulatory requirement.

This guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance have been approved under OMB control number 0910–0032.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments 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.

VI. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: February 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–05016 Filed 3–4–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1153]

Implementation of the FDA Food Safety Modernization Act Provision Requiring FDA To Establish Pilot Projects and Submit a Report to Congress for the Improvement of Tracking and Tracing of Food; Request for Comments and for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and information.

SUMMARY: In September 2011, the Food and Drug Administration (FDA or the Agency) asked the Institute of Food Technologists (IFT) to execute product tracing pilot projects as described in the FDA Food Safety Modernization Act (FSMA). FDA recently released a report from IFT on these pilot projects, entitled ''Pilot Projects for Improving Product Tracing along the Food Supply System.'' FDA is announcing the opening of a docket to provide stakeholders and other interested parties an opportunity to submit comments and information that will help the Agency as it forms its own recommendations, to be contained in the Agency's report to Congress, and as it implements the FSMA provisions relating to the tracking and tracing of food.

DATES: Submit electronic or written comments and information by April 4, 2013.

ADDRESSES: You may submit comments and information, identified by Docket No.FDA–2012–N–2012–N–1153, by any of the following methods:

Electronic Submissions

Submit electronic comments and information in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments and information.

Written Submissions

Submit written submissions in the following way:

- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2012–N–1153 for this notice. All comments and information received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments and information, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments and information received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sherri A. McGarry, Office of Foods, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 1212, Silver Spring, MD 20903, 301–796–3851.

SUPPLEMENTARY INFORMATION:

I. Background

A. FSMA Provisions Regarding Enhanced Tracking and Tracing of Food and Recordkeeping

On January 4, 2011, the President signed FSMA (Pub. L. 111–353) into law. Section 204 of FSMA, 21 U.S.C. 2223, relates to enhanced tracking and tracing of food and recordkeeping. As part of this provision, FDA must, among other things, complete the following:

1. Establish pilot projects in coordination with the food industry to explore and evaluate methods for rapid and effective tracking and tracing of foods. FDA is required to submit a report to Congress on the findings of the pilot projects together with FDA's recommendations for improving tracking and tracing of food;

2. Assess the costs and benefits associated with the adoption and use of several product tracing technologies and the feasibility of such technologies for different sectors of the food industry (including small businesses);

3. To the extent practicable in assessing the costs, benefits, and