Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.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. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Samie Allen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1533, Silver Spring, MD 20993–0002, 301–796–6055, or Tami Belouin, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In the letters dated September 27, 2007, from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the U.S. Senate and the Chairman of the Committee on Energy and Commerce of the U.S. House of Representatives setting out the goals of section 201(c) of MDUFA II, Title II of the Food and Drug Administration Amendments of 2007 (FDAAA) (21 U.S.C. 379i note), FDA committed to developing a guidance document that describes an interactive review process between FDA and industry for specific medical device premarket submissions. Further, during discussions with representatives of the medical device industry in the development of the Agency's recommendations for MDUFA III, Title II of the Food and Drug Administration Safety and Innovation Act, Public Law 112–144 (July 9, 2012), 126 Stat. 1002 (21 U.S.C. 301 note), the Agency proposed process improvements to provide further transparency into the review process, including new communication commitments.

This guidance describes four types of communication that occur during the review of a medical device premarket submission. The four types of communication are: Acceptance Review Communication, Substantive Interaction, Interactive Review, and Missed MDUFA Decision Communication.

## II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on communication during a medical device premarket submission review to provide further transparency into, and to increase the efficiency of, the review process. 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 statute and regulations.

## III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.* To receive ''Types of Communication During the Review of Medical Device Submissions,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1804 to identify the guidance you are requesting.

## 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 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

## 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.*

Dated: February 27, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–05015 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–2000–D–0598]; (Formerly Docket No. 00D–1631)]**

### International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Draft Revised Guidance for Industry on ''Studies To Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing'' (VICH GL23(R)); Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft revised guidance for industry (GFI #116) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing'' (VICH GL23(R)). This draft revised guidance is a revision of a final guidance on the same topic for which a notice of availability was published in the **Federal Register** of January 4, 2002, and has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). In this draft revised VICH guidance the recommendation for a second test to evaluate the potential of a chemical to produce chromosomal effects is being revised. The draft revised guidance indicates that the potential of a chemical to produce chromosomal effects can be evaluated using one of the the following three tests: An in vitro chromosomal aberrations test using metaphase analysis, which detects both clastogenicity and aneugenicity; an in vitro mammalian cell micronucleus test, which detects the activity of

clastogenicity and aneugenicity; or a mouse lymphoma test, which, with modification, can detect both gene mutation and chromosomal damage. This draft revised VICH guidance document is intended to facilitate the mutual acceptance of safety data necessary for the establishment of acceptable daily intakes for veterinary drug residues in human food by the relevant regulatory authorities.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft revised guidance before it begins work on the final version of the revised guidance, submit either electronic or written comments on the draft revised guidance by May 6, 2013.

**ADDRESSES:** Submit written requests for single copies of the draft revised 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 draft revised guidance document.

Submit electronic comments on the draft revised 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:** Tong Zhou, Center for Veterinary Medicine, (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8120, *Tong.Zhou@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft revised guidance for industry (GFI #116) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing'' (VICH GL23(R)). 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 (ICH) 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 International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (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; U.S. FDA; U.S. Department of Agriculture; Animal Health Institute; Japanese Veterinary Pharmaceutical Association; Japanese Association of Veterinary Biologics; and 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. Draft Revised Guidance on Genotoxicity Testing

In December 2012, the VICH Steering Committee agreed that a draft revised guidance document entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing'' (VICH GL23(R)) should be made available for public comment. This draft revised VICH guidance is a revision of a final guidance on the same topic for which a notice of availability was published in the **Federal Register** of January 4, 2002 (67 FR 603). In this draft revised guidance the recommendation for a second test to evaluate the potential of a chemical to produce chromosomal effects is being revised. The draft revised guidance indicates that the potential of a chemical to produce chromosomal effects can be evaluated using one of the the following three tests: (1) An in vitro chromosomal aberrations test using metaphase analysis, which detects both clastogenicity and aneugenicity; (2) an in vitro mammalian cell micronucleus test, which detects the activity of clastogenicity and aneugenicity; or (3) a mouse lymphoma test, which, with modification, can detect both gene mutation and chromosomal damage. This VICH draft revised guidance is intended to facilitate the mutual acceptance of safety data necessary for the establishment of acceptable daily intakes for veterinary drug residues in human food by the relevant regulatory authorities. The objective of this draft revised guidance is to ensure international harmonization of genotoxicity testing.

The draft revised guidance is a product of the Safety Expert Working Group of the VICH. Comments about this draft revised guidance document will be considered by FDA and the VICH Safety Expert Working Group.

## III. Paperwork Reduction Act of 1995

This draft revised 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 revised guidance have been approved under OMB control number 0910–0032.

## IV. Significance of Guidance

This draft revised 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 ''must,'' ''shall,'' ''require'' or ''requirement'' unless FDA is using these words to describe a statutory or regulatory requirement.

This draft revised VICH guidance when finalized, will represent 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.

**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