

docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance 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](mailto: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 Harmonization 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 Toxicity Testing**

In the **Federal Register** of September 4, 2002 (67 FR 56569), FDA published the notice of availability of the VICH draft guidance, giving interested persons until October 4, 2002 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 from October 10 to 11, 2002, the VICH Steering Committee endorsed the guidance for industry, VICH GL31.

A variety of toxicological evaluations are performed to establish the safety of veterinary drug residues in human food. The objective of this guidance is to establish recommendations for an internationally harmonized 90-day repeat-dose testing.

**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 unless specifically supported by statute or regulation, mandatory words such as "must," "shall," and "will" in the original VICH documents have been substituted with "should" or "it is recommended."

This guidance document represents the agency's current thinking on establishing the safety of veterinary drug residues in human food. 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 guidance 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 should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance document and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**V. Electronic Access**

Persons with Internet access may obtain copies of the guidance document entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (90-Day) Toxicity Testing" (VICH GL31), from the CVM home page at <http://www.fda.gov/cvm>.

Dated: October 31, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2003D-0474]

**International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products; Draft 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;" Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability for comments of a draft guidance document for industry (#159) entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI" (VICH GL-36). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).