

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.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](mailto:lmulliga@cvm.fda.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In recent years, many important initiatives have been undertaken by regulatory authorities, industry associations, and individual sponsors 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 reduce the 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 United States' 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 industry in Australia/New Zealand, one representative from the Government of Canada, and one representative from industry in 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 Guidance on Microbiological Acceptable Daily Intakes**

The VICH Steering Committee held a meeting on May 8, 2003, and agreed that the draft guidance document entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing" (VICH GL-37) should be made available for public comment. This draft 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 (ADIs) for veterinary drug residues in human food. This draft guidance was developed after consideration of the current practices for evaluating veterinary drug residues in human food in the European Union, Japan, United States, Australia, New Zealand, and Canada. It also took account of available data from subchronic and chronic toxicity studies.

FDA and the VICH Expert Working Group on Toxicity Safety will consider comments about the draft guidance document. Information collection is covered under Office of Management and Budget control number 0910-0032.

##### **III. Significance of Guidance**

This draft document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115).

The draft VICH guidance (#160) represents the agency's current thinking

on the general approach to establish a microbiological ADI. This guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative method as long as it satisfies the requirements of the applicable statutes and regulations.

##### **IV. Comments**

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written or electronic comments regarding this draft guidance document. Written comments should be submitted to the Division of Dockets Management (see **ADDRESSES**). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance 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**

Comments may be submitted electronically on the Internet at <http://www.fda.gov/dockets/ecomments> (select "[docket number] entitled 'Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing' (VICH GL-37)."

Copies of the draft guidance may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm>.

Dated: October 14, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Indian Health Service**

##### **Health Professions Preparatory, Pregraduate and Indian Health Professions Scholarship Programs**

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice of Availability of Funds for Health Professions Preparatory, Pregraduate, and Indian Health Professions Scholarship Programs for Fiscal Year (FY) 2004.

**SUMMARY:** The Indian Health Service (IHS) is publishing a Notice of Availability of Funds for Health Professions Preparatory, Pregraduate,