regard to drugs marketed in the United States that do not have required FDA approval for marketing. This document will, when finalized, supersede section 440.100 entitled ''Marketed New Drugs Without Approved NDAs or ANDAs'' (CPG 7132c.02) of the Compliance Policy Guide (CPG). It applies to any new drug required to have FDA approval for marketing, including new drugs covered by the over-the-counter (OTC) review.

DATES: Submit written or electronic comments on the draft guidance by December 22, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self addressed adhesive label to assist the office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sakineh Walther, Center for Drug Evaluation and Research (HFD–316), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–827–8964.

SUPPLEMENTARY INFORMATION:

I. Background

In the United States, as many as several thousand drug products are marketed illegally without required FDA approval. The manufacturers of these drugs have neither received FDA approval to legally market their drugs, nor have the drugs been marketed in accordance with a final over-the-counter (OTC) monograph. The drug approval and OTC monograph processes play an essential role in ensuring that all drugs are both safe and effective. Manufacturers of new drugs that lack required approval, including those that are not marketed in accordance with an OTC monograph, have not provided FDA with evidence demonstrating that their products are safe and effective. Therefore, FDA has an interest in taking steps to either encourage the manufacturers of these products to obtain the required evidence and comply with the approval provisions of the Federal Food, Drug, and Cosmetic Act (the act), or to remove the products from the market. FDA recognizes that these goals need to be achieved without adversely affecting public health, imposing undue burdens on consumers, or unnecessarily disrupting the market.

In general, in recent years, FDA has employed a risk-based enforcement approach to marketed unapproved drugs that includes efforts to identify illegally marketed drugs, prioritization of those drugs according to potential public health concerns or other impacts on the public health, and subsequent regulatory followup. Some of the specific actions the agency has taken have been precipitated by evidence of safety or effectiveness problems that has either come to our attention during inspections or was brought to our attention by outside sources.

The goals of this draft guidance are to address the following issues: (1) Clarify for FDA personnel and the regulated industry how FDA intends to exercise its enforcement discretion regarding unapproved drugs and (2) emphasize that illegally marketed drugs must obtain FDA approval.

The draft guidance reflects the agency's desire to address this issue with policies that are predictable, reasonable, and supportive of the public health. The agency's approach encourages companies to comply with the drug approval process, but it also seeks to minimize disruption to the marketplace and to safeguard consumer health when there are potential safety risks. The draft guidance explains that FDA will continue to give priority to enforcement actions involving unapproved drugs: (1) with potential safety risks, (2) that lack evidence of effectiveness, and (3) that constitute health fraud. It also explains how the agency intends to address those situations in which a firm obtains FDA approval to sell a drug that other firms have long been selling without FDA approval.

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 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.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed 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. 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.

III. Electronic Access

Persons with access to the Internet can obtain the guidance at *http://www.fda.gov/cder/guidance/index.htm*.

Dated: October 15, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–26753 Filed 10–20–03; 3:00 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0466]

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: Repeat-Dose (Chronic) Toxicity Testing;'' 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 (#160) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing'' (VICH GL–37). 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). This draft VICH guidance document establishes recommendations for internationally harmonized repeat-dose chronic toxicity testing.

DATES: Submit written or electronic comments on the draft guidance by November 24, 2003 to ensure their adequate consideration in preparation of the guidance document. General comments on agency guidance documents are welcome at any time.

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.

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.

[FR Doc. 03–26697 Filed 10–22–03; 8:45 am]

BILLING CODE 4160–01–S

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,