

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001D-0357]

International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products; Guidance for Industry on Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#141) entitled “Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing” (VICH GL28). This guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from a guidance regarding pharmaceuticals for human use, which was adopted by the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use (ICH). The objective of this VICH guidance document is to help ensure that the assessment of carcinogenic potential is appropriate to human exposure to residues of veterinary drugs in human food in the European Union, Japan, and the United States.

DATES: Submit written or electronic comments 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 requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic or written comments at any time on the 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 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 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 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 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 in Canada, and one representative from the 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. Guidance on Carcinogenicity Testing

In the **Federal Register** of August 28, 2001 (66 FR 45319), FDA published the notice of availability of the VICH draft guidance, giving interested persons until September 28, 2001 to submit comments. No comments were received. At a meeting held on October 10–11, 2002, the VICH Steering Committee endorsed the guidance for industry, VICH GL28.

This guidance is one of a series of VICH guidances developed 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 guidance on the overall strategy for the evaluation of veterinary drug residues in human food (“VICH Guidance on General Testing Approach”) will be made available at a later time.

VICH developed this guidance after consideration of the existing ICH guidances for pharmaceuticals for human use: “Final Guideline on the Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals”; and “S1B Testing for Carcinogenicity of Pharmaceuticals.” Notices of availability for these guidances published in the **Federal Register** of March 1, 1996, (61 FR 8153) and February 23, 1998, (63 FR 8983) respectively. The guidance has been adapted for veterinary use by the VICH from the aforementioned guidances regarding pharmaceuticals for human use. VICH also took into account the Organisation for Economic Cooperation and Development methodological guidances and the current practices for evaluating the safety of veterinary drug residues in human food in the European Union, Japan, the United States of America, Australia and New Zealand. (Information collection for new animal drug applications is covered under OMB control number 0910–0032.)

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 carcinogenicity testing for 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, at any time, submit written comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the 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

Copies of the guidance document entitled “Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing” (VICH GL28) may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm>.

Dated: May 18, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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