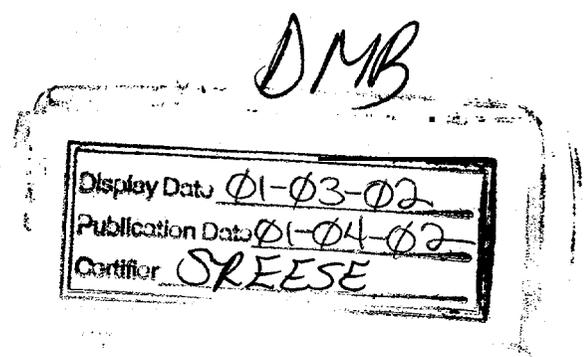


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1630]



International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Final Guidance on “Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Toxicity Testing” (VICH GL22); 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 (#115) entitled “Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Toxicity Testing” (VICH GL22). This final 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). This final VICH guidance document recommends a basic battery of tests that can be used to evaluate the reproduction safety of veterinary drug residues in human food.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the final 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 final guidance document.

Submit written comments on the final guidance to the Dockets Management Branch (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 final 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 the 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; 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.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand, and one representative from the industry in Australia/New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confederation Mondiale de L'Industrie de la Sante Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Guidance on Reproduction Studies

In the **Federal Register** of December 19, 2000 (65 FR 79373), FDA published the notice of availability of VICH draft guidance entitled "Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies" giving interested persons until February 20, 2001, to submit comments. FDA received no comments. The final guidance was submitted to the VICH Steering Committee. At a meeting held on June 28, 2001, the VICH Steering Committee endorsed the final guidance for industry entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Reproductive Toxicity Testing" (VICH GL22).

In order to establish the safety of veterinary drug residues in human food, a number of toxicological evaluations are recommended, including the assessment of any risks to reproduction. The objective of this guidance is to ensure international harmonization of reproduction toxicity testing, which is appropriate for the evaluation of risks to reproduction from long-term, low-dose exposures, such as may be encountered from the presence of veterinary drug residues in food.

The current final 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 for veterinary drug residues in human food by the relevant regulatory authorities. The guidance on the overall strategy for the safety evaluation of veterinary residues in human food (VICH Guidance on General Testing Approach) will be made available at a later time. VICH GL22 was developed after consideration of the existing ICH guidance for pharmaceuticals for human use on "Detection of

Toxicity to Reproduction for Medicinal Products” and its addendum, “Toxicity to Male Fertility,” in conjunction with the current practices for evaluating veterinary drug residues in human food in the European Union, Japan, the United States, Australia, and New Zealand.

This final level 1 guidance document was developed under the VICH process and is consistent with FDA’s good guidance practices regulation (21 CFR 10.115). 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 alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations. (Information collection is covered under OMB Control Nos. 091 O-01 17 and 0910-0032.)

III. Comments

As with all of FDA’s guidances, the public is encouraged to submit written or electronic comments with new data or other new information 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 Dockets Management Branch (address above) regarding this guidance document. 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 document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Comments may also be submitted electronically on the Internet site at <http://www.fda.gov/dockets/ecomments>. Once on this Internet site, select OOD-1630 “Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Toxicity Testing” (VICH GL22) and follow the directions.

Copies of the final guidance document entitled "Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Toxicity Testing" (VICH GL22) may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm>.

D a t e d : 12/28/01

December 28, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01-???? Filed ??-??-01; 8:45 am]

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