

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 99D-2406]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Final Guidance for Industry entitled "Good Clinical Practice" (VICH GL9); 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 (No. 85) entitled "Good Clinical Practice" (VICH GL9). This guidance document has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The final VICH guidance is intended to provide a unified standard for designing, conducting, monitoring, recording, and reporting studies used in registration applications for approval of veterinary products submitted to the European Union, Japan, and the United States.

DATES: Submit written comments at any time. This guidance will be implemented July 1, 2001.

ADDRESSES: Submit written requests for a single copy of the final guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 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 at any time on the final guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail: fdadockets@oc.fda.gov.

FOR FURTHER INFORMATION CONTACT: Herman M. Schoenemann (HFV-120), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0220, e-mail: hschoene@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 recommendations. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical recommendations for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce the differences in technical recommendations for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use for several years to develop harmonized technical recommendations 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 recommendations 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; the European Medicines Evaluation Agency; the European Federation of Animal Health; 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.

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 Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Guidance on Good Clinical Practice

In the **Federal Register** of August 3, 1999 (64 FR 42135), FDA published the notice of availability of the draft guidance entitled "Good Clinical Practices" (VICH GL9), giving interested persons until September 2, 1999 to submit comments. After considering the comments received, FDA made principally editorial changes. The final guidance was submitted to the VICH Steering Committee. At a meeting held on June 14 through 16, 2000, the VICH Steering Committee endorsed the final guidance for industry, VICH GL9.

The guidance is intended to be an international ethical and scientific quality standard for designing, conducting, monitoring, recording, auditing, analyzing, and reporting clinical studies evaluating veterinary products. This final guidance document is intended to be consistent with the laws of the European Union, Japan, and the United States.

VICH GL9 is a revision of and will replace CVM guidance No. 58 entitled "Good Target Animal Studies Practices: Investigators and Monitors." In addition, there are some minor conflicts between this guidance and recent CVM guidance No. 56 entitled "Protocol Development Guideline for Clinical Effectiveness and Target Animal Safety Trials," and No. 104 entitled "Guidance for Industry: Content and Format of Effectiveness and Target Animal Safety Technical Sections and Final Study Reports for Submission to the Division of Therapeutic Drugs for Non-Food Animals." Until the center revises these guidances, sponsors should follow the recommendations in VICH GL9 when differences among the guidances occur.

This Level 1 final guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents FDA's current thinking on design and conduct of all clinical studies of veterinary products in the target species. 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 method may be used as long as it satisfies the requirements of applicable statutes and regulations.

Information collected is covered under OMB control number 0910-0032.

III. Electronic Access

Copies of the final guidance documents entitled "Good Clinical Practice" (VICH GL9) may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm>. Comments may also be submitted electronically on the Internet at <http://www.fda.gov/dockets/ecomments>. Once on this Internet site, select "99D-2406 Good Clinical Practice" and follow the directions.

IV. Comments

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this final guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend this guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this final guidance document at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments

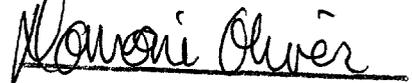
should be identified with the docket number found in brackets in the heading of this document. A copy of this final guidance document and received comments are available in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 5/7/01
May 7, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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