

DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date	8-3-99
Revision Date	8-2-99
Certifier	<i>[Signature]</i>

[Docket No. 99D-2406]

**International Cooperation on Harmonisation of Technical Requirements for
 Registration of Veterinary Medicinal Products (VICH); Draft Guidance on VICH GL9
 Good Clinical Practices; Request for Comments**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of the following draft guidance document entitled: VICH GL9 "Good Clinical Practices." This draft guidance document was developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). It 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 by *(insert date 30 days after date of publication in the Federal Register)*. FDA must receive comment before the deadline in order to ensure their consideration.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance documents and the docket number found in the heading of this document.

Copies of the draft guidance document entitled "Good Clinical Practices" may be obtained on the Internet from the CVM home page at "<http://www.fda.gov/cvm/fda/TOCs/guideline.html>". Persons without Internet access may submit written requests for single copies of the draft guidances

to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT:

Regarding VICH: Sharon R. Thompson (HFV-3), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1798, e-mail: "sthompso@bangate.fda.gov".

Regarding the guidance document: 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, 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 seeking scientifically-based harmonized technical requirements 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 Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) for several years to develop harmonized technical requirements for the approval of human pharmaceutical products among the European Union, Japan and the United States. The VICH is a parallel initiative for veterinary products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary products in the European Union, Japan and the United States, and includes input from both regulatory and industry representatives.

The VICH meetings are held under the auspices of the Office International des Epizooties (OIE). 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; 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 Mercado Comun Sudamericano (MERCOSUR) representing Argentina, Brazil, Uruguay, and Paraguay, and one representative from Federacion Latino-Americana de la Industria para la Salud Animal. 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 participates in the VICH Steering Committee meetings.

At a meeting held on October 20 through 22, 1998, the VICH Steering Committee agreed that the draft guidance document entitled "Good Clinical Practices" should be made available for public comment.

The draft 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. Comments about these draft guidance documents will be considered by the FDA and the VICH Good Clinical Practices Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidance and publish it as future guidance for sponsors of domestic animal drug approvals or as proposed regulations for future comment and final rulemaking.

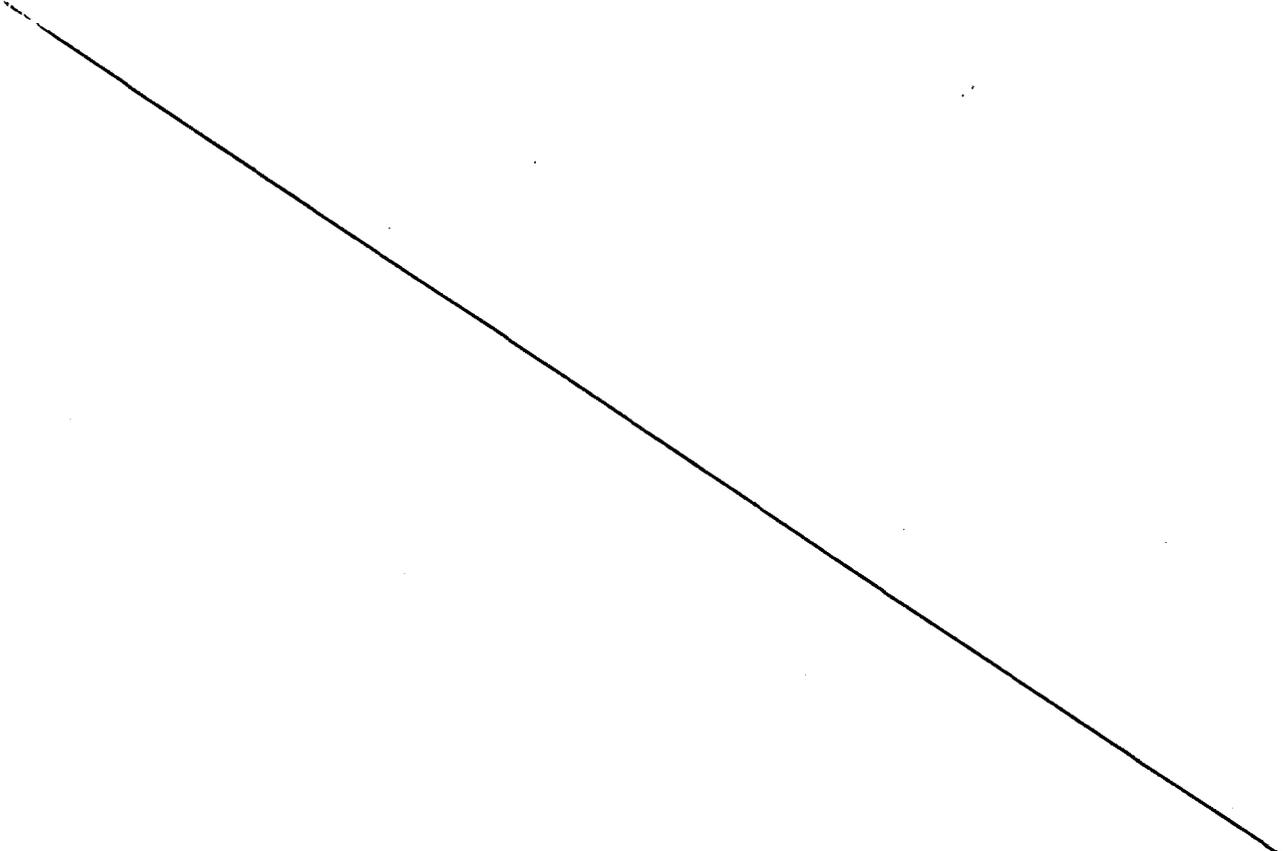
This document has been revised to conform to FDA's good guidance practices regulations (62 FR 8961, February 27, 1997). For example, the document has been designated "guidance"

rather than “guideline.” Since guidance documents are not binding, mandatory words such as “must” in the original VICH document have been substituted with the verb “should.” These revisions are identified by placing the original word in brackets followed by the substitute verb.

This draft document represents current FDA thinking on design and conduct of all clinical studies of veterinary products in the target species. The document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternate approaches may be used if they satisfy the requirements of applicable statutes, regulations, or both.

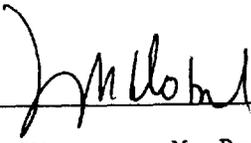
II. Comments

Interested persons should submit written comments on or before (*insert date 30 days after date of publication in the Federal Register*) 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 should be identified with the docket number found

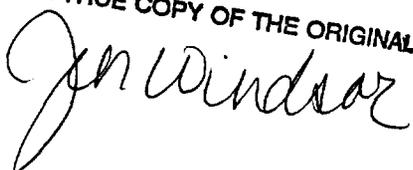


in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/27/99
July 27, 1999



Margaret M. Dotzel
Acting Associate Commissioner for Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL


[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F