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Issuance Date	10/8/99
Publication Date	10/12/99
Certifier	J. W. [Signature]

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 98D-0566]

**International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Final Guidances entitled "Stability Testing of New Veterinary Drug Substances and Medicinal Products" (VICH GL3); "Stability Testing of New Veterinary Dosage Forms" (VICH GL4); "Stability Testing: Photostability Testing of New Veterinary Drug Substances and Medicinal Products" (VICH GL5); Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of three final guidances for industry entitled "Stability Testing of New Veterinary Drug Substances and Medicinal Products" (VICH GL3), "Stability Testing of New Veterinary Dosage Forms" (VICH GL4), and "Stability Testing: Photostability Testing of New Veterinary Drug Substances and Medicinal Products" (VICH GL5). These guidances have been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH) from guidances regarding pharmaceuticals for human use, which were adopted by the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use (ICH). These VICH documents provide guidance on stability testing of new animal drugs and new dosage forms of new animal drugs included as part of new animal drug applications (referred to as registration applications in the guidances) submitted to the European Union, Japan, and the United States.

**DATES:** You may submit written comments at anytime.

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**ADDRESSES:** Copies of the final guidance documents entitled “Stability Testing of New Veterinary Drug Substances and Medicinal Products” (VICH GL3), “Stability Testing of New Veterinary Dosage Forms” (VICH GL4), and “Stability Testing: Photostability Testing of New Veterinary Drug Substances and Medicinal Products” (VICH GL5) may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm/fda/mappgs/vich.html>. Persons without Internet access may submit written requests for single copies 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.

You may submit written comments any time on the final guidance documents to the Policy and Regulations Team (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

**FOR FURTHER INFORMATION CONTACT:**

Regarding VICH: Sharon Thompson, Center for Veterinary Medicine (HFV-3), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1798, E-mail, “[sthompso@cvm.fda.gov](mailto:sthompso@cvm.fda.gov)”, or

Robert C. Livingston, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-5903, E-mail, “[rlivings@cvm.fda.gov](mailto:rlivings@cvm.fda.gov)”.

Regarding the guidance documents: William G. Marnane, Center for Veterinary Medicine (HFV-140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6966. E-mail, “[wmarnane@cvm.fda.gov](mailto:wmarnane@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.

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 pharmaceutical products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary pharmaceutical 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). During the initial phase of the VICH, an OIE representative chairs the VICH Steering Committee.

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.

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 Stability Testing**

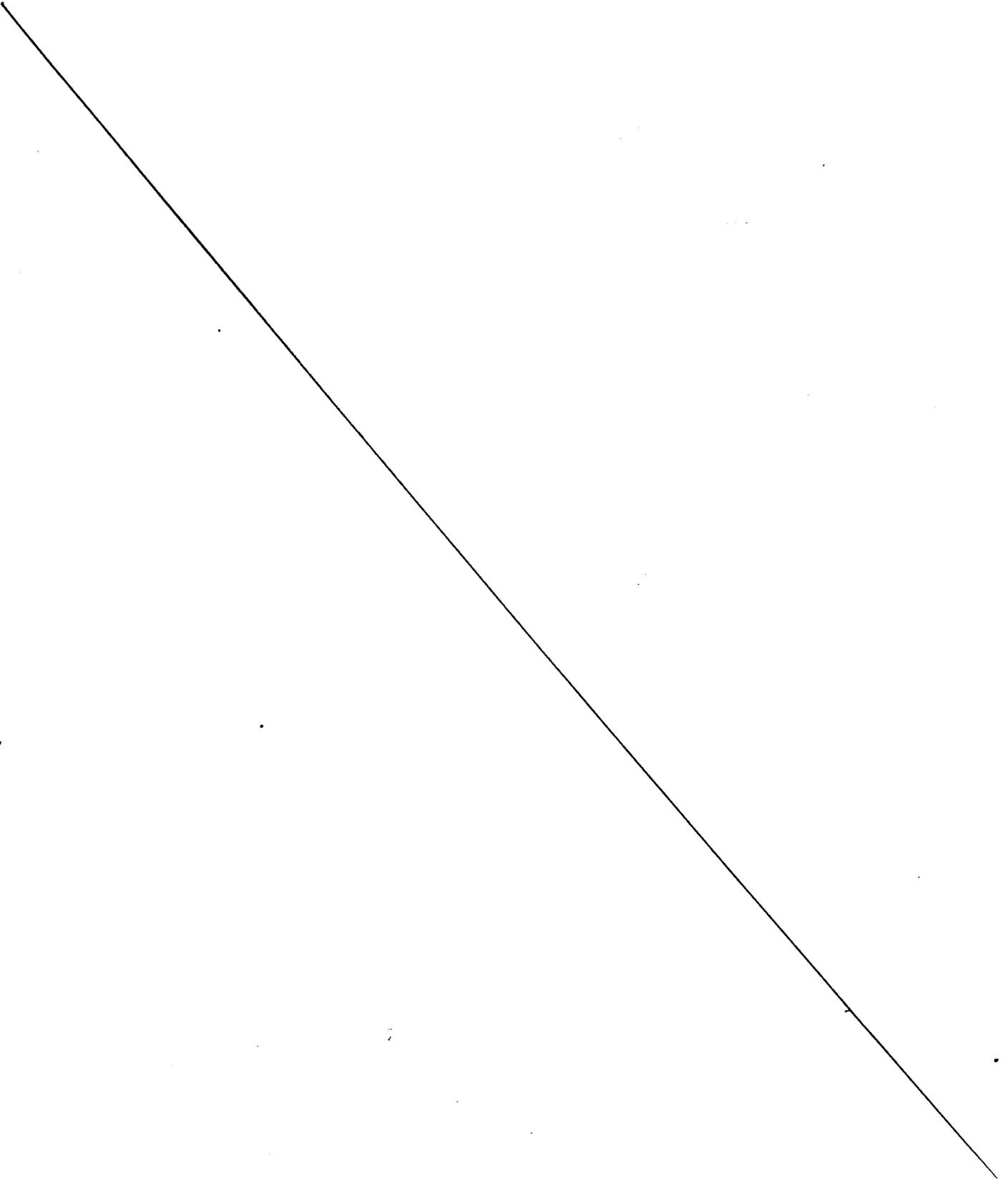
These three guidances are entitled “Stability Testing of New Veterinary Drug Substances and Medicinal Products” (VICH GL3), “Stability Testing of New Veterinary Dosage Forms” (VICH GL4), and “Stability Testing: Photostability Testing of New Veterinary Drug Substances and Medicinal Products” (VICH GL5). They have been adapted for veterinary use by the VICH from guidances regarding pharmaceuticals for human use which were adopted by the ICH and published in the **Federal Register** of September 22, 1994 (59 FR 48753), May 9, 1997 (62 FR 25634), and May 16, 1997 (62 FR 27115).

In the **Federal Register** of July 30, 1998 (63 FR 40721), FDA published these VICH guidances in draft form, giving interested persons until August 31, 1998, to submit comments. After consideration of comments received, final draft guidances were submitted to the VICH steering committee. At a meeting held on May 20, 1999, the VICH Steering Committee endorsed the three final draft guidances for industry, VICH GL3, VICH GL4, and VICH GL5.

VICH GL3 addresses the generation of stability information that should be included in submissions for new animal drug applications in the European Union, Japan, and the United States. VICH GL4 is an annex to VICH GL3 and supplements that document by providing specific guidance on what should be submitted regarding stability of new dosage forms by the new animal drug applicant, after the original submission of stability information made in a new animal drug application. VICH GL5 is also an annex to VICH GL3 and supplements that document by providing guidance on basic protocol for photostability testing for new animal drugs. These guidances will be implemented in May of 2000.

These guidances represent the FDA's current thinking on stability testing of new animal drugs and new dosage forms of new animal drugs. They do not create or confer any rights for or on

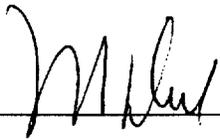
any person and does not operate to bind FDA or the public. You may use alternative methods as long as they satisfy the requirements of applicable statute and regulation.



As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to these guidances. The comments in the docket will be periodically reviewed, and, where appropriate, the guidances will be amended. The public will be notified of any such amendments through a notice in the **Federal Register**.

Dated: 9/30/99  
September 30, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



Margaret M. Dotzel  
Acting Associate Commissioner for Policy



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

BILLING CODE 4160-01-F