

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 99D-2249]

International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Final Guidance on Stability Testing for Medicated Premixes (VICH GL8); 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 (#91) entitled “Stability Testing for Medicated Premixes (VICH GL8).” 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). This final guidance document is an annex to the parent guidance VICH GL3 entitled “Stability Testing of New Veterinary Drug Substances and Medicinal Products.” This final guidance document is the annex and addresses the recommendations for stability testing of veterinary medicinal Type A medicated articles (referred to as medicated premix drug products in the final guidance) intended for submission for approval to the European Union, Japan, and the United States.

DATES: You may submit written comments at any time.

ADDRESSES: Copies of the final guidance document entitled “Stability Testing for Medicated Premixes (VICH GL8)” 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 at any time on the final guidance document 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 the VICH: Sharon R. 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, 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.

Regarding the guidance document: 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.

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 International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use 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 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 Épizooties (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; the European Medicines Evaluation Agency; the European Federation of Animal Health; the 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 Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

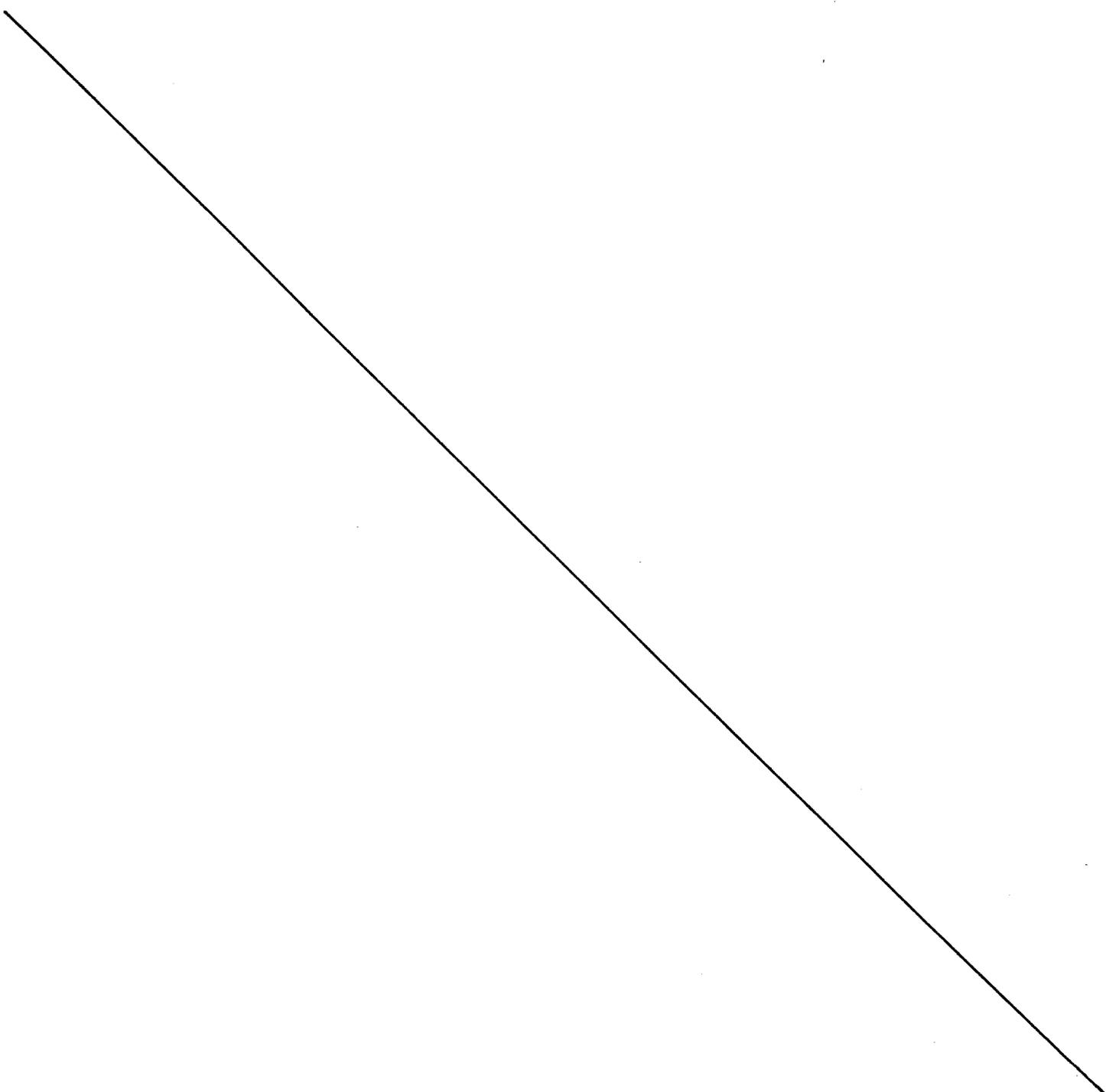
II. Guidance on Stability Testing

In the **Federal Register** of July 22, 1999 (64 FR 39515), FDA published the draft guidance entitled "Stability Testing for Medicated Premixes (VICH GL8)," giving interested persons until August 23, 1999, to submit comments. After consideration of comments received the final draft guidance was submitted to the VICH Steering Committee. At a meeting held on November 16 through 19, 1999, the VICH Steering Committee endorsed the final draft guidance, VICH GL8, for industry.

VICH GL8 addresses the generation of acceptable stability information for submission in new animal drug applications (referred to as registration applications in the final guidance) for Type

A medicated articles containing new molecular entities. This guidance will be implemented in May 2000.

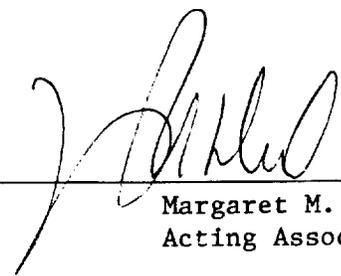
This final guidance document represents the agency's current thinking on acceptable stability testing of Type A medicated articles. The document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternate approaches may be used if they satisfy the requirements of applicable statutes, regulations, or both.



III. 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 guidance. The comments in the docket will be periodically reviewed, and, where appropriate, the guidance will be amended. The public will be notified of any such amendments through a notice in the **Federal Register**.

Dated: 3/3/2000
March 3, 2000



Margaret M. Dotzel
Acting Associate Commissioner for Policy

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