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: September 30, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4070]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance on ''Quality of Biotechnological Products in the Veterinary Field: Stability Testing of Biotechnological/Biological Products'' (VICH GL17); Availability; 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 on the draft guidance for industry entitled ''Quality of Biotechnological Products in the Veterinary Field: Stability Testing of Biotechnological/Biological Products'' (VICH GL17). This 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 Registration of Pharmaceuticals for Human Use (ICH). This draft VICH document is intended to provide guidance to applicants regarding the stability studies that should be conducted and the stability data that should be provided in support of new animal drug applications (NADA's) (referred to as marketing applications in the draft guidance) for veterinary biotechnological/biological products that are regulated by FDA.

DATES: Submit written comments by November 12, 1999.

ADDRESSES: Send 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 document and the docket number found in the heading of this document.

Copies of the draft guidance document entitled ''Quality of Biotechnological Products in the Veterinary Field: Stability Testing of Biotechnological/Biological Products'' (VICH GL17) 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 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.

FOR FURTHER INFORMATION CONTACT:

Regarding 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 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 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 meetings are held under the auspices of the Office International des Épizooties (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; 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 participates in the VICH Steering Committee meetings.

II. Guidance on Stability Testing of Biotechnological/Biological Products

This draft guidance entitled ''Quality of Biotechnological Products in the Veterinary Field: Stability Testing of Biotechnological/Biological Products'' (VICH GL17), has been adapted for veterinary use by the VICH from a guidance regarding pharmaceuticals for human use which was adopted by the ICH and published in the **Federal Register** of July 10, 1996 (61 FR 36466). At a meeting held on May 18 through 20, 1999, the VICH Steering Committee agreed that VICH GL17 should be made available for public comment.

This draft guidance document is intended to provide guidance to applicants regarding the stability studies that should be conducted and the stability data that should be provided in support of NADA's for veterinary biotechnological/biological products that are regulated by FDA. It is intended to supplement the tripartite VICH GL3 guidance entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products.'' Biotechnological/biological products have distinguishing characteristics to which consideration should be given in any well-defined testing program designed to confirm their stability during the intended storage period. For such products, in which the active components are typically proteins and/or polypeptides, maintenance of molecular conformation and biological activity is dependent on noncovalent as well as covalent forces. The products are particularly sensitive to environmental factors such as temperature changes, oxidation, light, ionic content, and shear. In order to ensure maintenance of biological activity and to avoid degradation, stringent conditions for their storage are usually necessary.

Comments about this draft guidance document will be considered by the FDA and the VICH Quality Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidance and publish it as future guidance.

This draft guidance document has been revised to conform to FDA's good guidance practices (62 FR 8961, February 27, l997) . For example, the document has been designated ''guidance'' rather than ''guideline.'' Because guidance documents are not binding, mandatory words such as ''must,'' ''shall,'' and ''will'' in the original VICH documents have been substituted with ''should.''

This draft guidance represents the agency's current thinking on stability testing of veterinary biotechnological/biological products. The document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. You may use alternate methods as long as they satisfy the requirements of the applicable statute and regulation.

III. Comments

General comments are welcome at any time, however, in order to ensure consideration at the next meeting, interested persons should submit written comments on or before November 12, 1999, to the Dockets Management Branch (address above) regarding this draft 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 draft guidance 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: September 30, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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