

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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[Docket No. 00D-1632]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance on “Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER’s)” (VICH GL24); Availability; Request for Comments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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance for industry (#117) entitled “Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER’s)” (VICH GL24). This draft guidance has been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft guidance is intended to describe the reporting system for identification of possible adverse events following the use of marketed veterinary medicinal products (VMP’s) submitted to the European Union, Japan, and the United States.

DATES: Submit written comments concerning the draft guidance to ensure their adequate consideration in preparation of the final document by *[insert date 30 days after date of publication in the Federal Register]*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments concerning the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD

20852. Identify comments with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

Copies of the draft guidance entitled "Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)" (VICH GL24) may be obtained on the Internet from the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 Persons without Internet access may submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.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 Carole R. Andres, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6524, e-mail: candres1@cvm.fda.gov.

Regarding the guidance document: Neal Bataller, Center for Veterinary Medicine (HFV-214), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0163, e-mail: nbatalle@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 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 then 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 Registration 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 pharmaceutical products. The VICH is concerned with developing harmonized technical requirements for the approval of VMP's 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 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. Draft Guidance on AER's

The VICH Steering Committee held a meeting on June 15, 2000, and agreed that the draft guidance entitled "Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)" (VICH GL24) should be made available for public comment.

The draft guidance is intended to describe the harmonized and common systems, common definitions, and standardized terminology within pharmacovigilance. Harmonization of those

elements between the VICH regions facilitates the reporting responsibilities for the marketing authorities or drug sponsors, many with worldwide activities. More specifically, the draft guidance presents the terms and definitions intended to harmonize other previously used terms referring to similar pharmacovigilance concepts. The draft guidance describes the various components of information flow within the pharmacovigilance system. Finally, the draft guidance defines data elements that are sufficiently comprehensive to cover complex reports from most sources for the purpose of electronic transmission. (This information collected is authorized by OMB Control No. 0910-0012).

III. Significance of Guidance

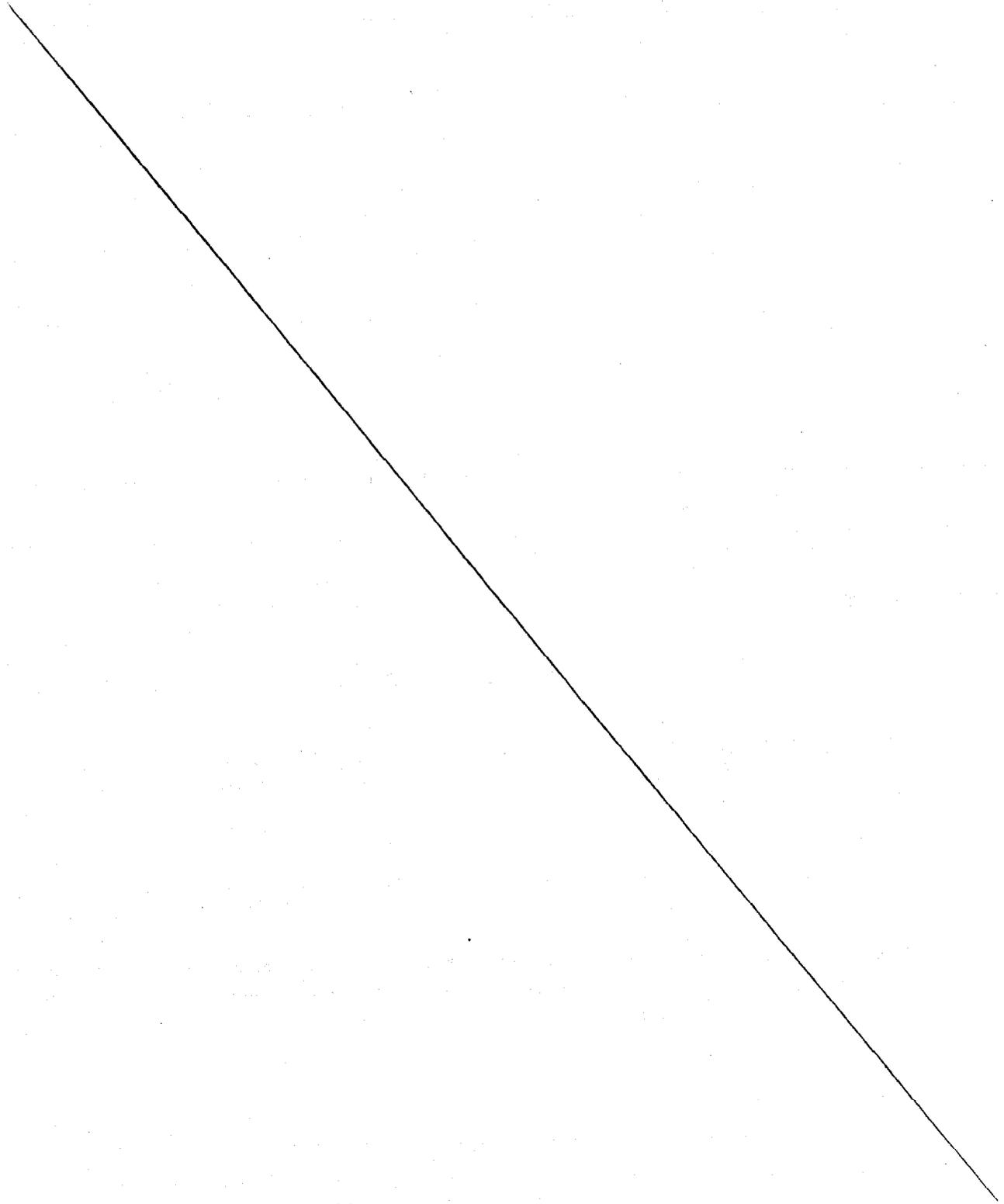
This draft guidance is being issued consistent with FDA's good guidance practices (65 FR 56468, September 19, 2000). For example, the documents have been designated "guidance" rather than "guideline." Because guidance documents are not binding, unless specifically supported by statute or regulation, mandatory words such as "must," "shall," and "will" in the original VICH documents have been substituted with "should." Similarly, words such as "requirement" or "acceptable" or phrases such as "minimum standards" or "minimum needed" have been replaced by "recommendation" or "recommended" as appropriate to the context.

The draft guidance represents the agency's current thinking on the management of AER's of approved new animal drugs. This draft guidance does not create or confer any rights for or on any person and will 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.

IV. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments to ensure adequate consideration in preparation of the final guidance by *[insert date*

30 days after date of publication in the **Federal Register**]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with



the docket number found in brackets in the heading of this document. A copy of the draft guidance 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: 12/8/00
December 8, 2000

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Ramona Oliver

M. Dotzel
Margaret M. Dotzel
Associate Commissioner for Policy

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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