

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000D–1632] (formerly 00D–1632)

International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products; Draft Revised Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports; Request for Comments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft revised guidance for industry (#117) entitled “Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER’s)” VICH GL24. This draft revised guidance, which updates a draft guidance on the same topic for which a notice of availability was published in the **Federal Register** of December 18, 2000 (the 2000 draft guidance), has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft revised guidance is intended to describe the reporting system for identification of possible adverse events following the use of marketed veterinary medicinal products (VMPs) submitted to the European Union, Japan, and the United States.

DATES: Submit written comments on the draft revised guidance by [*insert date 30 days after date of publication in the Federal Register*], to ensure their

adequate consideration in preparation of the final guidance document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft revised guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft revised guidance document.

Submit written comments on the draft revised guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the full title of the draft revised guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Lynn Post, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9062, e-mail: lynn.post@fda.hhs.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

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then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonization 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. VICH is a parallel initiative for veterinary medicinal products. 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 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; 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.

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 the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH steering committee meetings.

II. Draft Guidance on Adverse Event Reports

In November 2005, the VICH steering committee held a meeting and agreed that the draft guidance document entitled “Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER’s)” VICH GL24, should be revised and made available for a second public comment period. This draft revised guidance updates the draft guidance on the same topic for which a notice of availability was published in the **Federal Register** of December 18, 2000 (65 FR 79111). The draft revised guidance clarifies the 2000 draft guidance, adds information, and provides consistency with more recently published VICH guidances. The draft revised guidance is the product of the Pharmacovigilance Expert Working Group of VICH. Comments on this draft will be considered by FDA and the Pharmacovigilance Expert Working Group.

The draft revised guidance describes 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 revised guidance presents the terms and definitions intended to harmonize other previously used terms referring to similar pharmacovigilance concepts. This draft revised guidance describes a system for the management of adverse drug event reports following the use of marketed veterinary medicinal products.

This draft revised guidance includes revised text on the definition of a veterinary medicinal product, definition of international birth date, and third country reporting. Data elements for the submission of AERs were removed

from this draft revised guidance, but are addressed in a separate VICH draft guidance document entitled “Pharmacovigilance of Veterinary Medicinal Products: Data Elements for Submission of Adverse Event Reports” VICH GL42. The notice of availability for VICH GL42 is published elsewhere in this issue of the **Federal Register**.

III. Paperwork Reduction Act of 1995

This draft revised guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 514.80 have been approved under OMB control number 0910–0284 (expiration date 06/30/2006).

IV. Significance of Guidance

Under part 10 (21 CFR part 10), specifically § 10.115(i)(3), when issuing draft guidance documents that are the product of international negotiations, FDA need not apply § 10.115(i)(2), which states that guidance documents must not include mandatory language such as “shall,” “must,” “required,” or “requirement,” unless FDA is using these words to describe a statutory or regulatory requirement. However, any final guidance document issued according to § 10.115(i) must contain the elements in § 10.115(i)(2). In this draft revised guidance, any language that is mandatory under U.S. laws and/or regulations is followed by a citation to the appropriate statutory or regulatory provision. In accordance with § 10.115(i)(3), any mandatory language in this draft revised guidance that does not describe a statutory or regulatory requirement will be revised in the final guidance document to comply with § 10.115(i)(2).

The draft revised VICH guidance represents the agency's current thinking on the management of AERs of approved new animal drugs. This draft revised 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.

V. Comments

This draft revised guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft revised guidance document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft revised guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Electronic comments may also be submitted electronically on the Internet at <http://www.fda.gov/dockets/ecomments>. Once on this Internet site, select Docket No. 2000D-1632, entitled "Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)" VICH GL24 and follow the directions.

Copies of the draft revised guidance document entitled “Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER’s)” VICH GL24 may be obtained on the Internet from the Center for Veterinary Medicine home page at <http://www.fda.gov/cvm>.

Dated: April 26, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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