

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date 6-20-07
Publication Date 6-21-07
Certifier L. CLAWSON
DDM

[Docket No. 2002D-0005] (formerly 02D-0005)

International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Revised Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms (VICH GL30); Request for Comments; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comments of a revised draft guidance for industry (#143) entitled "Revised Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms" (VICH GL30). This revised draft guidance, which updates a draft guidance on the same topic for which a notice of availability was published in the **Federal Register** of February 6, 2002 (the 2002 guidance), has been developed for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 VICH guidance document describes the specific data elements to be used for the submission and exchange of spontaneous adverse event reports (AERs) between marketing authorization holders (MAHs) and regulatory authorities (RAs).

DATES: Submit written or electronic comments on the revised draft guidance by [*insert date 30 days after date of publication in the Federal Register*], to

cv0718

2002D.0005

NAD2

ensure their adequate consideration in preparation of the final document.

General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the revised draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised draft guidance document.

Submit written comments on the revised draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 revised draft 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

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

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. 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. Revised Draft Guidance on Controlled Lists of Terms

In June 2006, the VICH steering committee agreed that a revised draft guidance entitled “Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms” (VICH GL30), should be made available for public comment. The draft guidance is a revision of a guidance on the same topic for which a notice of availability was published in the **Federal Register** of February 6, 2002 (67 FR 5605). This revised draft guidance clarifies the 2002 guidance, adding information, and providing consistency with more recently published VICH guidances.

This draft VICH guidance document describes the specific data elements to be used for the submission and exchange of spontaneous AERs between MAHs and RAs. Although the revised draft guidance includes, as Appendix A, a proposed list of terms, FDA prefers the list of terms maintained by the National Cancer Institute’s *NCI Thesaurus* and would like to refer to the *NCI Thesaurus* in the final guidance. FDA invites comments regarding which list of terms (Appendix A or the *NCI Thesaurus*) would be the best choice to further the goals set forth in this revised draft guidance. Since Appendix A was included in the revised draft guidance for discussion purposes only, it has not yet been formally considered within the VICH process. FDA expects that the list of terms included in Appendix A will be discussed by a task force chosen from the members of the VICH pharmacovigilance expert working group.

III. Paperwork Reduction Act of 1995

This revised draft 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 section III of the revised draft guidance have been approved under OMB Control No. 0910–0284.

IV. Significance of Guidance

This draft document, developed under the VICH process, has been revised to conform to FDA’s good guidance practices regulation (21 CFR 10.115). For example, the document has been designated “guidance” rather than “guideline.” In addition, guidance documents must not include mandatory language such as “shall,” “must,” “require,” or “requirement,” unless FDA is using these words to describe a statutory or regulatory requirement.

The draft VICH guidance (#143) is consistent with the agency’s current thinking on this topic. This 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

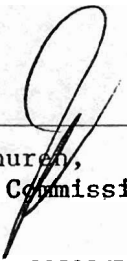
This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written or electronic comments regarding this draft guidance document to the Division of Dockets Management (see **ADDRESSES**). Submit a single 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 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 Web site <http://www.fda.gov/dockets/ecomments>. Once on this Internet site, select Docket No. 2002D-0005 entitled “Revised Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms” (VICH GL30), and follow the directions.

Copies of the draft guidance document entitled "Revised Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms" (VICH GL30) may be obtained on the Internet from the Center for Veterinary Medicine home page at <http://www.fda.gov/cvm>.

Dated: 6/13/07
June 13, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

BILLING CODE 4160-01-S



**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**