4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0588]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (GFI #214) entitled "Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data" (VICH GL35). This guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document is intended to provide recommended standards to construct a single Adverse Event Report (AER) electronic message to transmit VICH GL42 contents to all member regions and Product Problem Reports (PPR) to FDA for veterinary medicinal products. Please note that VICH GL42 has been harmonized in GFI #188, "Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine."

DATES: Submit either electronic or written comments on Agency guidance at any time.

ADDRESSES: Submit written requests for single copies of the 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 request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Margarita Brown, Center for Veterinary Medicine (HFV-240), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9048, CVMAESupport@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 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 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 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, 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.

Six 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, one representative from the industry of Canada, one representative from the government of South Africa, and one representative from the industry of South Africa. 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. Guidance on Electronic Standards for Transfer of Data

In the Federal Register of September 15, 2011 (76 FR 57060), FDA published a notice of availability for a draft guidance document entitled "Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data" (VICH GL35). Interested persons were given until November 14, 2011, to comment on the draft guidance. FDA received a few comments on the draft guidance, and those comments, as well as those received by other VICH member regulatory agencies, were considered as the guidance was finalized. The guidance

announced in this document finalizes the draft guidance dated September 15, 2011. The final guidance is a product of the Pharmacovigilance Expert Working Group of the VICH.

In order to allow for electronic exchange of this information between stakeholders, further specification of the field descriptors and their relationships, including agreement on format of the electronic message is essential. This VICH guidance document is intended to provide recommended standards to construct a single electronic message to transmit data elements for submission of AERs to all member regions. The need to transfer and disseminate information quickly, accurately and easily between Regulatory Authorities and Marketing Authorization Holders on a worldwide scope is especially pertinent to the notification and assimilation of information for pharmacovigilance. Whereas the recommended definition of the pharmacovigilance information has been set forth within the draft guidance entitled, "Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)" (VICH GL24), and the final guidances entitled "Pharmacovigilance of Veterinary Medicinal Products: Controlled Lists of Terms" (VICH GL30) and "Pharmacovigilance of Veterinary Medicinal Products: Data Elements for Submission of Adverse Event Reports" (VICH GL42), this guidance defines recommended electronic standards for transfer of data. Please note that VICH GL42 has been harmonized in GFI #188, "Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine."

III. Significance of Guidance

This guidance, 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 guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

This 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 this guidance have been approved under OMB control number 0910-0645.

V. Comments

Interested persons may submit either electronic comments regarding this document to www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. 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

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm or http://www.regulations.gov.

Dated: December 4, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014-28830 Filed 12/09/2014 at 8:45 am; Publication Date: 12/10/2014]