4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1177]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Electronic Exchange of Documents: Electronic File Format; Guidance for Industry; 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 #225) entitled "Electronic Exchange of Documents: Electronic File Format" (VICH GL53). 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 cover the electronic file format specifications for individual documents and collections of multiple related documents that do not need subsequent modification during the regulatory procedure and are utilized for electronic exchange between industry and regulatory authorities in the context of regulatory approval of veterinary medicinal products.

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

ADDRESSES: Submit written requests for single copies of this guidance to the Policy and Regulations Staff (HFV-6), 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 to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Scott Fontana, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0656, scott.fontana@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; 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.

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 Exchange of Documents: Electronic File Format

In the Federal Register of August 28, 2014 (79 FR 51342), FDA published a notice of availability for a draft guidance entitled "Electronic Exchange of Documents: Electronic File Format" (VICH GL53) giving interested persons until October 27, 2014, to comment on the draft guidance. FDA received two 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 notice finalizes the draft guidance dated August 2014.

The final guidance is a product of the Electronic File Format Expert Working Group of the VICH.

This VICH guidance document provides recommendations to industry regarding electronic file format specifications (e.g., file format, file size, file security, and cross-referencing) for individual documents and collections of multiple related documents for the transfer of electronic regulatory information in support of applications for the approval of veterinary medicinal products. This guidance applies to communication or data exchanged as documents in the context of all regulatory procedures where regulatory authorities accept electronic transfer of such documents. This can include but is not limited to applications for initial marketing authorizations, related pre-submission or post-authorization procedures, applications for maximum residue limits, clinical trial applications, drug/active substance master files, or requests for regulatory or scientific advice.

III. Significance of Guidance

This guidance, developed under the VICH process, has been revised to conform with FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated "guidance" rather "guideline". In addition, guidance documents must not include mandatory language such as "shall", "must", "require", or "requirements", unless FDA is using these words to describe a statutory or regulatory requirement. The guidance represents the current thinking of FDA on electronic exchange of documents: electronic file format. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it 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 21 CFR part 514 have been approved under OMB control number 0910-0032.

V. Comments

Interested persons may submit either electronic comments regarding this document to http://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, and will be posted to the docket at http://www.regulations.gov.

VI. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/cvm or http://www.regulations.gov.

Dated: August 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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