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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1999-D-2955]

Revised Guidance for Industry on Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (Revision), VICH GL18(R); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry (#100) entitled "Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (Revision)" VICH GL18(R). This revised guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The guidance is intended to recommend acceptable amounts of residual solvents in new animal drugs (referred to as pharmaceuticals or veterinary medicinal products in this guidance) for the safety of the target animal as well as for the safety of human consumers of products derived from treated food producing animals. It is intended to assist in developing new animal drug applications (referred to as marketing applications in this guidance) submitted to the European Union, Japan, and the United States.

DATES: Submit either electronic or written comments on Agency guidances 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 requests. 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:

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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 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. 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, the U.S. Food and Drug Administration, 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 Guidance on Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients

In the Federal Register of August 17, 2010 (75 FR 50771), FDA published a notice of availability for a draft revised guidance entitled "Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (Revision) VICH GL18(R)" giving interested

persons until October 18, 2010, to comment on the draft revised guidance. This draft incorporated a lower permissible daily exposure limit for N-Methypyrrolidone, which is still being kept in Class 2, and placed tetrahydrofuran into Class 2 from Class 3. Based on comments received from the draft revised guidance, additional information was added in section 3.2 of this guidance to include reference to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use guideline entitled "Impurities: Guideline for Residual Solvents (Q3C(R4))." The revised guidance announced in this notice finalizes the draft revised guidance announced on August 17, 2010. The revised guidance is a product of the Quality Expert Working Group of the VICH.

III. Paperwork Reduction Act of 1995

This 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 this document have been approved under OMB control number 0910-0032.

IV. Significance of Guidance

This revised 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 revised VICH guidance (GFI #100) 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

Interested persons may, at any time, submit either electronic or written comments regarding this revised guidance document to the Division of Dockets Management (see addresses). It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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: October 27, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.