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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier A. Corbin

Food and Drug Administration

[Docket No. 1999D–2145]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Revised Guidance for Industry on Impurities in New Veterinary Medicinal Products (Revision); 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 (#93) entitled "Impurities in New Veterinary Medicinal Products (Revision)" VICH GL11(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). This revised document is intended to assist in developing registration applications for approval of veterinary medicinal products submitted to the European Union, Japan, and the United States. The revised guidance addresses only those impurities in new veterinary medicinal drug products classified as degradation products.

DATES: Submit written or electronic 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 (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one

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

FOR FURTHER INFORMATION CONTACT: Dennis Bensley, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956, e-mail: *dennis.bensley@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 for several years in the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use 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. 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 Guidance on Impurities in New Veterinary Medicinal Products

In the **Federal Register** of January 10, 2006 (71 FR 1543), FDA published a notice of availability for a draft revised guidance entitled "Impurities in New Veterinary Medicinal Products (Revision)" VICH GL11(R), which gave interested persons until February 9, 2006, to comment on the draft revised guidance. No comments were received. The revised guidance announced in

this document finalizes the draft revised guidance announced on January 10, 2006. The revised guidance is a product of the Quality Expert Working Group of the VICH.

The document is intended to provide guidance for new animal drug applications on the content and qualification of impurities in new veterinary medicinal products produced from chemically synthesized new veterinary drug substances not previously registered in a country, region, or member State.

III. 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 sections II through VI of the guidance 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 (guidance for industry #93) is consistent with the agency's current thinking on impurities in new veterinary drug medicinal products. 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 written or electronic comments regarding the revised guidance document to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two copies of written comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination 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 from either the CVM home page (*http://www.fda.gov/cvm*) or the Division of Dockets Management Web site (*http://www.fda.gov/ohrms/dockets/default.htm*).

Dated: 11/12/07
November 12, 2007.

Randall W. Lutter,
Deputy Commissioner for Policy.

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