

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0166]

DDM

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**International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on Target Animal Safety for Veterinary Pharmaceutical Products, VICH GL43, Request for Comments; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability for comments of a draft guidance document for industry (#185) entitled "Draft Guidance for Industry on Target Animal Safety for Veterinary Pharmaceutical Products," VICH GL43. This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal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 has been developed as a harmonized standard to aid in development of mutually acceptable target animal safety (TAS) studies for the relevant governmental regulatory bodies.

**DATES:** Submit written or electronic comments on the draft guidance by [*insert date 30 days after publication in the Federal Register*], to ensure their adequate consideration in preparation of the final document.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**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and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 request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Laura Hungerford, Center for Veterinary Medicine, (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6439, e-mail: *laura.hungerford@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. Draft Guidance on Target Animal Safety**

The VICH steering committee held a meeting in December 2006 and agreed that the draft guidance document entitled “Draft Guidance for Industry on Target Animal Safety for Veterinary Pharmaceutical Products,” VICH GL43 should be made available for public comment. This draft VICH guidance

document has been developed as a harmonized standard to aid in development of mutually acceptable TAS studies for the relevant governmental regulatory bodies. This draft guidance document is intended to cover TAS studies for any Investigational Veterinary Pharmaceutical Product used in the following species: Bovine, ovine, caprine, feline, canine, porcine, equine, and poultry (chickens and turkeys). Minor species and minor uses may be excluded from this guidance for local registration. The guidance does not provide information for the design of TAS studies in other species including aquatic animals. For other species, TAS studies should be designed following local guidance.

FDA and the VICH Expert Working Group will consider comments about the draft guidance document.

### **III. Paperwork Reduction Act of 1995**

This 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 1-5 of the draft guidance have been approved under OMB Control No. 0910–0032.

### **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 (GFI #185) 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.

#### **IV. Comments**

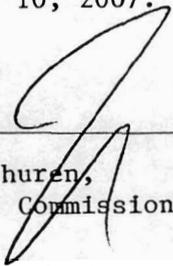
This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written or electronic comments regarding this draft guidance document to the Division of Dockets Management (see **ADDRESSES**). Submit a single 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.

#### **V. Electronic Access**

Electronic comments may also be submitted electronically on the Web site at <http://www.fda.gov/dockets/ecomments>. Once on this Internet site, select Docket No. 2007D-0166 entitled "Draft Guidance for Industry on Target Animal Safety for Veterinary Pharmaceutical Products," VICH GL43 and follow the directions.

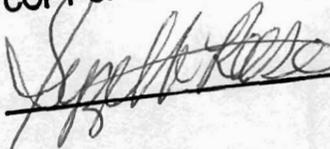
Copies of the draft guidance document entitled "Draft Guidance for Industry on Target Animal Safety for Veterinary Pharmaceutical Products," VICH GL43 may be obtained on the Web site from the Center for Veterinary Medicine home page at <http://www.fda.gov/cvm>.

Dated: 5/10/07  
May 10, 2007.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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