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Dated: September 12, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy, Food and Drug Administration.*

Dated: September 12, 2011.

**Alfred V. Almanza,**

*Administrator, Food Safety and Inspection Service.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-D-0163]

**International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Guidance for Industry on Studies To Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Metabolism Study To Determine the Quantity and Identify the Nature of Residues; 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 (#205) entitled "Guidance for Industry on Studies To Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Metabolism Study To Determine the Quantity and Identify the Nature of Residues (MRK)," (VICH GL46). 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 recommendations for internationally harmonized test procedures to study the quantity and nature of residues of veterinary drugs in food-producing animals.

**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 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:** Julia Oriani, Center for Veterinary Medicine (HFV-151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8204, [julia.oriani@fda.hhs.gov](mailto:julia.oriani@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:****I. Background**

FDA is announcing the availability of a guidance for industry (#205) entitled "Guidance for Industry on Studies To Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Metabolism Study To Determine the Quantity and Identify the Nature of Residues (MRK)" (VICH GL46). 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. 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 Biologists, 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. Guidance on Metabolism Study To Determine the Quantity and Identify the Nature of Residues**

In the **Federal Register** of April 12, 2010 (75 FR 18508), FDA published a notice of availability for a draft guidance entitled "Draft Guidance for Industry on Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Metabolism Study to Determine the Quantity and Identify the Nature of Residues (MRK) (VICH GL46)" which gave interested persons until May 12, 2010, 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. At a meeting held in February 2011, the VICH Steering Committee endorsed the final guidance for industry (VICH GL46). The guidance announced in this notice finalizes the draft guidance dated April 12, 2010.

This VICH guidance document is one of a series developed to facilitate the mutual acceptance by national/regional regulators of residue chemistry data for veterinary drugs used in food-producing animals. This guidance was prepared after consideration of the current national/regional requirements and recommendations for evaluating veterinary drug residues in the European Union, Japan, the United States, Australia, New Zealand, and Canada.

Although this guidance recommends a framework for metabolism testing, it is important that the design of the studies remains flexible. It is recommended that studies be tailored to sufficiently characterize the components of the residue of concern.

The human food safety evaluation of veterinary drug residues helps ensure that food derived from treated food-producing animals is safe for human consumption. As part of the data collection process, studies should be conducted to permit an assessment of the quantity and nature of residues in food derived from animals treated with a veterinary drug. These metabolism studies provide data on: (1) The depletion of residues of concern from edible tissues of treated animals at varying times after drug administration; (2) the individual components, or residues, that comprise the residue of

concern in edible tissues; (3) the residue(s) that can serve as marker for analytical methods intended for compliance purposes (*i.e.*, monitoring of appropriate drug use); and (4) the identification of a target tissue or tissues, as applicable to national or regional programs.

**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.

This 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 the 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 0910–0032.

**V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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: September 8, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-D-0166]

#### International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Guidance for Industry on Studies To Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Marker Residue Depletion Studies To Establish Product Withdrawal Periods; 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 (#207) entitled "Guidance for Industry on Studies To Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Marker Residue Depletion Studies To Establish Product Withdrawal Periods," (VICH GL48). 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 study design recommendations that will facilitate the universal acceptance of the generated residue depletion data to fulfill the national/regional requirements.

**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 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:** Julia Oriani, Center for Veterinary Medicine (HFV-151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8204, [julia.oriani@fda.hhs.gov](mailto:julia.oriani@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry (#207) entitled "Guidance for Industry on Studies To Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Marker Residue Depletion Studies To Establish Product Withdrawal Periods," (VICH GL48). 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. 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. Guidance on Marker Residue Depletion Studies To Establish Product Withdrawal Periods

In the **Federal Register** of April 12, 2010 (75 FR 18504), FDA published a notice of availability for a draft guidance entitled "Draft Guidance for Industry on Studies To Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Marker Residue Depletion Studies To Establish Product Withdrawal Periods," (VICH GL48), which gave interested persons until May 12, 2010, 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. At a meeting held in February 2011, the VICH Steering Committee endorsed the final guidance for industry (VICH GL48). The guidance announced in this notice finalizes the draft guidance dated April 12, 2010.

This VICH guidance document is one of a series developed to facilitate the mutual acceptance by national/regional regulators of residue chemistry data for veterinary drugs used in food-producing animals. This guidance was prepared after consideration of the current national/regional requirements and recommendations for evaluating veterinary drug residues in the European Union, Japan, the United States, Australia, New Zealand, and Canada.

As part of the approval process for veterinary medicinal products in food-producing animals, national/regional regulatory authorities require data from marker residue depletion studies in order to establish appropriate withdrawal periods in edible tissues, including meat, milk, and eggs. The objective of this guidance is to provide study design recommendations that will facilitate the universal acceptance of the generated residue depletion data to