

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 Comparative Metabolism Studies in Laboratory Animals

In the **Federal Register** of April 12, 2010 (75 FR 18507), FDA published a notice of availability for a draft guidance entitled "Draft Guidance for Industry on Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Comparative Metabolism Studies in Laboratory Animals (VICH GL47)," which gave interested persons until May 12, 2010, to comment on the draft guidance. FDA received a few comments on the draft guidance and those comments as well as those received by other VICH member regulatory agencies were considered as the guidance was finalized.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 GL47). The guidance announced in this notice finalizes the draft guidance dated April 12, 2010.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.

The objective of this guidance is to provide recommendations for internationally harmonized procedures to identify the metabolites of veterinary drugs produced by laboratory animals. The purpose of the comparative metabolism studies is to compare the metabolites of the animals used for toxicological testing to the residues of the veterinary drugs in edible tissues of food-producing animals in order to determine if the laboratory animals used for toxicological testing have been exposed to the metabolites that humans can be exposed to as residues in products of food-producing animal origin.

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 characterize the metabolites to which laboratory animals are auto-exposed during the toxicological testing of the veterinary drug. The purpose of these studies is to determine whether the metabolites that people will consume from tissues of target food-producing animals are also produced by metabolism in the laboratory animals used for the safety testing.

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](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–0165]

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: Validation of Analytical Methods Used in Residue Depletion Studies; 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 (#208) entitled "Guidance for Industry on Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Validation of Analytical Methods Used in Residue Depletion Studies," (VICH GL49). 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 a general description of the criteria that have been found by the European Union, Japan, the United States, Australia, New Zealand, and Canada to be suitable for the validation of analytical methods used in veterinary drug residue depletion studies.

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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry (#208) entitled "Guidance for Industry on Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Validation of Analytical Methods Used in Residue Depletion Studies," (VICH GL49). 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 the Validation of Analytical Methods Used in Residue Depletion Studies

In the **Federal Register** of April 12, 2010 (75 FR 18505), FDA published a notice of availability for a draft guidance entitled "Draft Guidance for Industry on Guidances for the Validation of Analytical Methods Used in Residue Depletion Studies," (VICH GL49), 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 GL49). The guidance announced in this document 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.

During the veterinary drug development process, residue depletion studies are conducted to determine the concentration of the residue or residues present in the edible products (tissues, milk, eggs, or honey) of animals treated with veterinary drugs. This information is used in regulatory submissions around the world. Submission of regulatory methods (*i.e.*, post approval control methods) and the validation requirements of the regulatory methods

are usually well defined by various regulatory agencies worldwide and might even be defined by national or regional law. However, the residue depletion studies are generally conducted before the regulatory methods have been completed. Oftentimes the in-house validated residue methods provide the framework for the methods submitted for regulatory monitoring. Harmonization of the validation requirements for methodology used during residue depletion studies and submitted to the regulatory agencies in support of the maximum residue limits and withdrawal periods should be achievable. It is the intent of this document to describe a validation procedure that is acceptable to the regulatory bodies of the European Union, Japan, the United States, Australia, New Zealand, and Canada for use in the residue depletion studies. This validated method could continue on to become the "regulatory method," but that phase of the process will not be addressed in any detail in this guidance. For purposes of this guidance, the term "acceptable" refers to the scientific evaluation of the analytical method in terms of the described validation criteria, not to acceptance of the analytical method as satisfying the applicable national/regional laws and regulations of any of the relevant regulatory bodies.

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-2011-D-0588]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#214) entitled "Draft Guidance for Industry, Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data" (VICH GL35). 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 is intended to provide recommended standards to construct a single electronic message to transmit data

elements for submission of adverse event reports (AERs) to all member regions.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by November 14, 2011.

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 electronic comments on the draft guidance to <http://www.regulations.gov>. 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.

FOR FURTHER INFORMATION CONTACT:

Margarita Brown, Center for Veterinary Medicine (HFV-240), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-9048, e-mail: margarita.brown@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry (#214) entitled "Draft Guidance for Industry, Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data (VICH GL35)." 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, U.S. FDA, 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 Electronic Standards for Transfer of Data

The VICH Steering Committee held a meeting in June 2010, and agreed that the draft guidance document entitled "Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data" (VICH GL35) should be made available for public comment. This draft VICH guidance document is intended to provide recommended standards to construct a single electronic message to transmit data elements for submission of AERs to all member regions.

The need to transfer and disseminate information quickly, accurately and easily between Regulatory Authorities (RA) and Marketing Authorization Holders (MAH) on a worldwide scope is especially pertinent to the notification and assimilation of information for pharmacovigilance. Whereas the recommended definition of the pharmacovigilance information has