

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. Draft Guidance on Study to Determine the Quantity and Identify the Nature of Residues

The VICH Steering Committee held a meeting on November 5, 2009, and agreed that the draft guidance document entitled "Draft Guidance for Industry on Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Metabolism Study to Determine the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 should be made available for public comment. This draft VICH guidance document is one of a series developed to facilitate the mutual acceptance of residue chemistry data for veterinary drugs used in food-producing animals. This guidance was prepared after consideration of the current requirements for evaluating veterinary drug residues in the European Union, Japan, 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 toxicological concern.

The human food safety evaluation of veterinary drugs assures that food derived from treated animals is safe for human consumption. As part of the data collection process, studies are 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 the following topics: (1) The depletion of residues of toxicological concern from edible tissues of treated animals at varying times after drug administration; (2) the individual components, or residues, that comprise the residue of toxicological concern in edible tissues; (3) the residue(s) that may 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.

FDA and the VICH Expert Working Group will consider comments about the draft guidance document.

III. Significance of Guidance

This draft 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.

The draft guidance, when finalized, will represent 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 applicable statutes and regulations.

IV. 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 sections 1–4 of this guidance have been approved under OMB Control No. 0910–0032.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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. 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 draft guidance at either <http://www.fda.gov/AnimalVeterinary/default.htm> or <http://www.regulations.gov>.

Dated: April 6, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–8228 Filed 4–9–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0342]

International Conference on Harmonisation; Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 10 on Polyacrylamide Gel Electrophoresis General Chapter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 10: Polyacrylamide Gel Electrophoresis General Chapter." The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance provides the results of the ICH Q4B evaluation of the Polyacrylamide Gel Electrophoresis General Chapter harmonized text from each of the three pharmacopoeias (United States, European, and Japanese) represented by the Pharmacopoeial Discussion Group (PDG). The guidance conveys recognition of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the recognition. The guidance is intended to recognize the interchangeability between the local regional pharmacopoeias, thus avoiding redundant testing in favor of a common testing strategy in each regulatory region. In the **Federal Register** of February 21, 2008 (73 FR 9575), FDA made available a guidance on the Q4B process entitled "Q4B Evaluation and

Recommendation of Pharmacopoeial Texts for Use in the ICH Regions.”

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling CBRE at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the 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.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert H. King, Sr., Center for Drug Evaluation and Research (HFD-003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4150, Silver Spring, MD 20993-0002, 301-796-1242; or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-0373.
Regarding the ICH: Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized

technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of August 14, 2009 (74 FR 41143), FDA published a notice announcing the availability of a draft tripartite guidance entitled “Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 10: Polyacrylamide Gel Electrophoresis General Chapter.” The notice gave interested persons an opportunity to submit comments by October 13, 2009.

After consideration of the comments received and revisions to the guidance, a final draft guidance entitled “Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 10: Polyacrylamide Gel Electrophoresis General Chapter” was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in October 2009.

The guidance provides the specific evaluation outcome from the ICH Q4B process for the Polyacrylamide Gel Electrophoresis General Chapter harmonization proposal originating from the three-party PDG. This guidance is in the form of an annex to the core

ICH Q4B guidance. When implemented, the annex will provide guidance for industry and regulators on the use of the specific pharmacopoeial texts evaluated by the ICH Q4B process. Following receipt of comments on the draft, no substantive changes were made to the annex.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The 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.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: April 6, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections