

TABLE 2.—Continued

Item No.	Title of Standard	Reference No. and Date
148	Standard Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials	ASTM F2250–03
149	Standard Test Method for Thickness Measurement of Flexible Packaging Materials	ASTM F2251–03 <sup>e1</sup>
150	Standard Practice for Evaluating Ink or Coating Adhesion to Flexible Packaging Materials Using Tape	ASTM F2252–03
151	Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method	ASTM F2338–04

#### IV. List of Recognized Standards

FDA maintains the agency's current list of FDA recognized consensus standards in a searchable database that may be accessed directly at FDA's Internet site at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

FDA will incorporate the modifications and minor revisions described in this document into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and minor revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often, if necessary.

#### V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under the new provision of section 514 of the act by submitting such recommendations, with reasons for the recommendation, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

#### VI. Electronic Access

In order to receive "Guidance on the Recognition and Use of Consensus Standards" via your fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800-899-0381 or 301-827-

0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 321 followed by the pound sign. Follow the remaining voice prompts to complete your request.

You may also obtain a copy of "Guidance on the Recognition and Use of Consensus Standards" by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this document announcing "Modification to the List of Recognized Standards, Recognition List Number: 012" will be available on the CDRH home page. You may access the CDRH home page at <http://www.fda.gov/cdrh>.

You may access "Guidance on the Recognition and Use of Consensus Standards," and the searchable database for FDA recognized consensus standards through the hyperlink at <http://www.fda.gov/cdrh/stdsprog.html>.

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at <http://www.fda.gov/cdrh/fedregin.html>.

#### VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) written or electronic comments regarding this document. Two copies of any mailed comments are to be submitted, 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. FDA will consider any comments received in determining whether to amend the current listing of

modifications to the list of recognized standards, Recognition List Number: 012. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: May 16, 2005.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 05-10626 Filed 5-26-05; 8:45 am]

**BILLING CODE 4160-01-S**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. 2005D-0199]

##### International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances; Request for Comments; Availability

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

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

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability for comments of a draft guidance document for industry (#176) entitled "Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances" (VICH GL39). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft VICH guidance document is intended to assist to the extent possible, in the establishment of a single set of recommended global

specifications for new veterinary drug substances and medicinal products. It provides guidance through recommendations on the setting and justification of acceptance criteria and the selection of test procedures for new drug substances of synthetic chemical origin, and new medicinal products produced from them, which have not been registered previously in the United States, the European Union, or Japan.

**DATES:** Submit written or electronic comments on the draft guidance by June 27, 2005, 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 requests. 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:** Dennis Bensley, Center for Veterinary Medicine, (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6956, e-mail: [dbensley@cvm.fda.gov](mailto:dbensley@cvm.fda.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

Harmonization 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; 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 Chemical Substance**

The VICH Steering Committee held a meeting in August 2004 and agreed that the draft guidance document entitled "Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances" (VICH GL39) should be made available for public comment. This draft VICH guidance addresses specifications, i.e., those tests, procedures, and acceptance criteria which play a major role in assuring the quality of the new veterinary drug substance and medicinal product at release and during shelf life. FDA and the VICH Safety Working Group will consider comments about the draft guidance document. Information collection is covered under OMB control number 0910-0032.

##### **III. 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." Because guidance documents are not binding, mandatory words such as "must," "shall," and "will" in the original VICH document have been substituted with "should." Similarly, words such as "require" or "requirement" have been replaced by "recommend" or "recommendation" as appropriate to the context. The draft VICH guidance (#176) is consistent with the agency's current thinking on the new veterinary drug substances and 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.

##### **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 to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft guidance 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. A copy of the draft 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.

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

Comments may be submitted electronically on the Internet at <http://www.fda.gov/dockets/ecomments>. Once on this Internet site, select Docket No. 2005D-0199 entitled "Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances" (VICH GL39), and follow the directions.

Copies of the draft guidance document entitled "Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances" (VICH GL39) may be obtained on the Internet from the Center for Veterinary Medicine's home page at <http://www.fda.gov/cvm>.

Dated: May 23, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005D-0200]

#### **International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on Specifications: Test Procedures and Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products; Request for Comments; Availability**

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

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

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document for industry (#177) entitled "Specifications: Test Procedures and Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products" (VICH GL40). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft VICH guidance document is intended to provide general principles through recommendations on the setting and justification, to the extent possible, of a uniform set of international specifications for biotechnological and biological products to support new marketing applications.

**DATES:** Submit written or electronic comments on the draft guidance by June 27, 2005, 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 requests. 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:**

Dennis Bensley, Center for Veterinary Medicine (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6956, e-mail: [dbensley@cvm.fda.gov](mailto:dbensley@cvm.fda.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. 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; 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 Biotechnological/Biological Veterinary Medicinal Products**

The VICH Steering Committee held a meeting in August 2004 and agreed that the draft guidance document entitled "Specifications: Test Procedures and Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products," (VICH GL40) should be made available for public comment. This draft VICH guidance document provides general principles through recommendations on the setting and justification, to the extent possible, of a uniform set of international specifications for biotechnological and biological products to support new marketing applications. The recommendations in this document apply to products composed of well-characterized proteins and polypeptides, and their derivatives which are isolated from tissues, body fluids, cell cultures, or produced using recombinant deoxyribonucleic acid (r-DNA) technology. Thus, the document covers the generation and submission of specifications for products such as cytokines, growth hormones and growth factors, insulins, and monoclonal antibodies. This document does not cover antibiotics, heparins, vitamins, cell metabolites, DNA products, allergenic extracts, vaccines, cells, whole blood, and cellular blood components.

FDA and the VICH Safety Working Group will consider comments about the draft guidance document. Information collection is covered under OMB control number 0910-0032.

##### **III. Significance of Guidance**

The draft guidance 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." Because guidance documents are not binding, mandatory