DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0456]

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.'' FDA developed this draft document to provide guidance about the appropriate use of national and international voluntary consensus standards in the preparation and evaluation of premarket submissions for medical devices. This document also discusses procedures for the appropriate use of consensus standards, both recognized and non-recognized, limitations on the use of consensus standards, and the content of a Declaration of Conformity to FDA-recognized consensus standards. This draft guidance is not final nor is it in effect at this time.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 11, 2014.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*.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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For devices regulated by CDRH: Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3632, Silver Spring, MD 20993–0002, 301–796–6287.

For devices regulated by CBER: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

I. Background

This draft guidance provides information to industry and FDA reviewers about the appropriate use of national and international voluntary consensus standards in the preparation and evaluation of premarket submissions for medical devices. This document intends to clarify and explain the regulatory framework, policies, and practices underlying the appropriate utilization of voluntary consensus standards in the premarket review program. Additionally, the guidance provides information about the general use of voluntary consensus standards as well as the appropriate use of the declaration of conformity to consensus standards that have been recognized by FDA under section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c). The draft guidance also proposes two changes in policy. The first proposal is for declarations of conformity to no longer be used when the submitter deviates from an FDA-recognized standard. The second proposal is for promissory statements indicating future conformance with a consensus standard to no longer be used. FDA intends to update other related guidance documents accordingly once this guidance is finalized. This guidance is not intended to address the specific content needed to support the approval or clearance of any particular premarket submission.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the appropriate use of voluntary consensus standards in premarket submissions for medical devices. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*. Persons unable to download an electronic copy of ''Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1770 to identify the guidance you are requesting.

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 21 CFR part 807, subpart E, and FDA Form 3654, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at *http://www.regulations.gov*.

Dated: May 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0288]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH GL51); Guidance for Industry on Statistical Evaluation of Stability Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of guidance for industry (GFI #219) entitled ''Guidance for Industry on Statistical Evaluation of Stability Data, VICH GL51.'' 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 on how to use stability data generated in accordance with the principles detailed in the VICH guidance entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products, GL3(R)'' to propose a retest period or shelf life in a registration application.

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 on the 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: Mai Huynh, Center for Veterinary Medicine, (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0669, *Mai.huynh@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. 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 governments 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 Statistical Evaluation of Stability Data

In the **Federal Register** of April 4, 2012 (77 FR 20406), FDA published a notice of availability for a draft guidance entitled ''Draft Guidance for Industry on Statistical Evaluation of Stability Data, VICH GL51.'' Interested persons were given until June 4, 2012, to comment on the draft guidance. FDA received several comments on the draft, and those comments, as well as those received by other VICH member regulatory agencies, were considered as the guidance was finalized. No substantive changes were made in finalizing this guidance document. The guidance announced in this document finalizes the draft guidance dated January 10, 2012. The final guidance is a product of the Quality Expert Working Group of the VICH.

This VICH guidance document provides recommendations on how to use stability data generated in accordance with the principles detailed in the VICH guidance entitled, ''Stability Testing of New Veterinary Drug Substances and Medicinal Products, GL3(R)'' to propose a retest period or shelf life in a registration application. This guidance describes when and how extrapolation can be considered when proposing a retest period for a drug substance or a shelf life for a veterinary medicinal product that extends beyond the period covered by available data from the stability study under the long-term storage condition.

This guidance addresses the evaluation of stability data that should be submitted in registration applications for new molecular entities and associated veterinary medicinal products. The guidance provides recommendations on establishing retest periods and shelf lives for drug