**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.*

[FR Doc. 2014–10905 Filed 5–12–14; 8:45 am]

**BILLING CODE 4160–01–P**

## 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

substances and veterinary medicinal products intended for storage at or below ''room temperature''. It covers stability studies using single- or multi-factor designs and full or reduced designs.

**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 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*.

**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: May 8, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–10952 Filed 5–12–14; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–N–0001]**

### Immune Responses to Enzyme Replacement Therapies: Role of Immune Tolerance Induction; Public Workshop

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

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cosponsorship with the National Organization for Rare Disorders (NORD), is announcing a 1-day public workshop entitled ''Immune Responses to Enzyme Replacement Therapies: Role of Immune Tolerance Induction.'' Partners and stakeholders planning the workshop also include representatives from academia, industry, and patients. The purpose of this workshop is to provide a forum to discuss the role of immune tolerance induction in patients receiving replacement biological products.

**DATES:** The public workshop will be held on June 9, 2014, from 8 a.m. to 5 p.m.

**ADDRESSES:** The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Bldg. 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

**FOR FURTHER INFORMATION CONTACT:** Maureen Dewey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0845, FAX: 301–796–9905, *Maureen.Dewey@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** FDA's Center for Drug Evaluation and Research, in co-sponsorship with NORD, is announcing a 1-day public workshop entitled ''Immune Responses to Enzyme Replacement Therapies: Role of Immune Tolerance Induction.'' The cosponsored workshop will facilitate an ongoing dialogue among relevant parties on issues related to the role of immune tolerance induction in enzyme replacement therapies. The workshop will discuss the impact of anti-drug and neutralizing antibodies on efficacy and safety of enzyme replacement therapies intended to treat patients with lysosomal storage diseases and the risks and benefits of implementing prophylactic immune tolerance regimens to preclude generation of these antibodies. Stakeholders, including patients and patient organizations, industry sponsors, academia, and FDA, will discuss challenging issues related to immune tolerance induction in enzyme replacement therapies.

*Registration:* There is no fee to attend the public workshop, but advanced online registration is requested. Space is limited, and registration will be on a first-come, first-served basis. To register online, please visit *https://events.rarediseases.org/?page_id=4&ee=13*. Onsite registration the day of the workshop will be available, but advanced registration is preferred.

If you need special accommodations due to a disability, please contact Maureen Dewey (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

*Transcripts:* Transcripts of the workshop will be available for review at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and at *http://www.regulations.gov* approximately 30 days after the workshop. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send faxed requests to 301–827–9267.

Dated: May 7, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–10933 Filed 5–12–14; 8:45 am]

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