OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov*.

Dated: March 28, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–8011 Filed 4–3–12; 8:45 am]

BILLING CODE 4120–01–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Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on Statistical Evaluation of Stability Data, VICH GL51; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#219) entitled ''Draft Guidance for Industry on Statistical Evaluation of Stability Data, VICH GL51.''

This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal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 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: 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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 4, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.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: Mai Huynh, Center for Veterinary Medicine, (HFV–142), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240–276–8273, *Mai.huynh@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry (#219) entitled, ''Draft Guidance for Industry on Statistical Evaluation of Stability Data, VICH GL51.'' 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, the European Medicines Evaluation Agency, the European Federation of Animal Health, the 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 Statistical Evaluation of Stability Data

The VICH Steering Committee held a meeting on November 14, 2011, and agreed that the draft guidance document entitled ''Draft Guidance for Industry on Statistical Evaluation of Stability Data, VICH GL51'' should be made available for public comment. This draft 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. This draft 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 draft guidance addresses the evaluation of stability data that should be submitted in registration applications for new molecular entities and associated veterinary medicinal products. The draft 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.

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 this draft guidance have been approved under OMB control number 0910–0032.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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.

VI. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: March 29, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–8039 Filed 4–3–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5630–N–02]

Rental Assistance Demonstration: Extension of Public Comment Period and Clarification of Demonstration Components

AGENCY: Office of the Assistant Secretary for Public and Indian Housing and Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: On March 8, 2012, HUD published a notice in the **Federal Register** inviting public comments on the demonstration notice posted on HUD's Web site entitled ''Rental Assistance Demonstration—Partial Implementation and Request for Comments'' (Program Notice). This notice extends the due date for the submission of comments on the Program Notice. In addition, HUD is taking this opportunity to clarify the scope of the demonstration that took effect on March 8, 2012.

DATES: *Comment Due Date:* The new date for the submission of comments on the Program Notice is April 23, 2012.

Effective Date: The effective date announced in the March 8, 2012, notice is unchanged. The provisions regarding the conversion of Rent Supp and RAP properties under Section III of the Program Notice were effective on March 8, 2012. The Moderate Rehabilitation (Mod Rehab) provisions detailed in Section II of the Program Notice are not in effect until HUD reviews the public comments and issues a notice in the **Federal Register**.

ADDRESSES: Interested persons are invited to submit comments on applicable parts of the March 8, 2012, notice to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. All submissions and communications must refer to ''Rental Assistance Demonstration: Notice of Web Availability and Request for Comments'' docket number FR–5630–N–01. There are two methods for submitting public comments.

1. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500.

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule. Also, to expedite review of public comments, it is recommended commenters should organize their comments by specific topical areas and section numbers and label those areas accordingly.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202–402–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service, toll-free, at 800–877–8339. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: To assure a timely response, please electronically direct requests for further information to this email address: *rad@hud.gov*. Written requests may also be directed to the following address: Office of Public and Indian Housing—RAD Program, Department of Housing and Urban Development, 451 7th Street SW., Room 2000; Washington, DC 20410.

SUPPLEMENTARY INFORMATION:

I. Background

On March 8, 2012, at 77 FR 14029, HUD published in the **Federal Register** a notice announcing HUD's Rental Assistance Demonstration (RAD) program, which provides the