4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0938]

Guidance for Industry; Guidance on Abbreviated New Drug Applications: Stability Testing of Drug Substances and Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance entitled "ANDAs: Stability Testing of Drug Substances and Products." FDA is recommending generic drug manufacturers follow the stability testing recommendations in the International Conference on Harmonisation (ICH) guidances Q1A (R2) through Q1E. The use of these ICH recommendations will standardize FDA's stability testing policies, which will help make the abbreviated new drug application (ANDA) review process more efficient.

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 Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. 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 to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Radhika Rajagopalan, Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., MPN2, rm. 243, HFD-640, Rockville, MD 20855, 240-276-8546.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "ANDAs: Stability Testing of Drug Substances and Products." Because of increases in the number and complexity of ANDAs and FDA's desire to standardize generic drug review, FDA is recommending that the generic drug industry follow the approach in the following stability related ICH guidances: (1) "Q1A (R2) Stability Testing of New Drug Substances and Products," November 2003; (2) "Q1B Photostability Testing of New Drug Substances and Products," November 1996; (3) "Q1C Stability Testing for New Dosage Forms," November 1996; (4) "Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products," January 2003; and (5) "Q1E Evaluation of Stability Data," June 2004. These guidances can be found on the FDA Guidances (Drugs) Web site under International Conference on Harmonisation – Quality at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm065005.htm. FDA also recommends that industry follow the ICH outlined definitions, glossaries, references, and attachments.

Although the ICH stability guidances were developed for new drug applications to ensure the stability of new drug substances and products, FDA believes the recommendations provided in the ICH guidances on stability testing also are appropriate for ANDAs. FDA is recommending that applicants follow the ICH stability guidances for all ANDA submissions

under section 505(j) of the Federal Food Drug, and Cosmetic Act (21 U.S.C. 355(j)) and relying on drug master files.

This guidance also replaces stability study storage condition recommendations made by the Office of Generic Drugs (OGD) in an August 18, 1995, letter to all ANDA applicants. That letter stated that OGD would accept ANDAs with the ICH recommended long-term room temperature conditions for stability studies, 25±2°C, 60±5 percent RH.

On September 25, 2012 (77 FR 58999), FDA announced the availability of draft guidance for industry on "ANDAs: Stability Testing of Drug Substances and Products." The public comment period closed on December 24, 2012. We are finalizing the guidance with minor changes and intend to publish a draft guidance to address the public comments in a question-and-answer format in the near future.

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 stability testing for generic drug substances and products. 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 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.

III. Electronic Access

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

Dated: June 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-14674 Filed 06/19/2013 at 8:45 am; Publication Date: 06/20/2013]