4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry on Abbreviated New Drug Applications: Stability Testing of Drug Substances and Products, Questions and Answers; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers." This draft guidance clarifies stability testing recommendations for abbreviated new drug applications (ANDAs) by providing responses to public comments in a questions-and-answers format. This draft guidance addresses public comments regarding FDA's recommendation to generic drug manufacturers to follow International Conference on Hamonisation (ICH) stability guidances Q1A (R2) through Q1E.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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, room 1061, Rockville, MD 20852.

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

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers." Because of increases in the number and complexity of ANDAs and FDA's desire to standardize generic drug review, on September 25, 2012 (77 FR 58999), FDA published a draft and on June 20, 2013 (78 FR 37231), published a final guidance recommending the generic industry follow the approach in the ICH stability-related 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 recommended that industry follow the ICH outlined definitions, glossaries, references, and attachments.

While carefully considering the public comments on the September 2012 draft guidance, we decided to publish a draft guidance in a questions-and-answers format. This draft guidance discusses stability testing relating to general questions, drug master files, drug product manufacturing and packaging, amendments to pending ANDA applications, and stability studies.

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 ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers. 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. The 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 parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively.

IV. Electronic Access

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

Dated: August 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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