



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Draft Guidance for Industry on Abbreviated New Drug Applications: Stability Testing of Drug Substances and Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “ANDAs: Stability Testing of Drug Substances and Products.” FDA is recommending that 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: 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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “ANDAs: Stability Testing of Drug Substances and Products.” Because of increases in numbers of ANDAs and their complexity, the FDA is considering standardizing stability testing policies by adopting recommendations 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. FDA is also considering adopting 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 are appropriate for ANDAs as well. This guidance contains FDA’s recommendation that ANDAs submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), and the drug master files that support ANDAs, follow the stability recommendations provided in the ICH stability guidances.

This guidance also replaces stability study storage condition recommendations made in an August 18, 1995, letter that the Center for Drug Evaluation and Research’s (CDER’s) Office of Generic Drugs (OGD) sent to all ANDA applicants, which is available on CDER’s Web site: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064995.htm>. The letter stated that OGD would accept ANDAs with the ICH recommended long term room temperature conditions for stability studies, $25 \pm 2^{\circ}\text{C}$, 60 ± 5 percent RH.

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 stability testing of drug substances and products for ANDAs. 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 to the Division of Dockets Management (see ADDRESSES) either electronic or written 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, 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.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: September 18, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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