4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0880]

Draft Guidance for Industry on Generic Drug User Fee Amendments of 2012: Questions and Answers (Revision 1); Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Generic Drug User Fee Amendments of 2012: Questions and Answers (Revision 1)." The Generic Drug User Fee Amendments of 2012 (GDUFA) is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA enables FDA to assess user fees to support critical and measurable enhancements to FDA's generic drugs program. GDUFA also requires that generic drug facilities, sites, and organizations located around the world provide identification information annually to FDA. This guidance is intended to provide updated answers to common questions from the generic drug industry and other interested parties involved in the development and/or testing of generic drug products regarding the requirements and commitments of GDUFA.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Jaewon Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., rm. 4145, Silver Spring, MD 20993, 301-796-6707, AskGDUFA@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

GDUFA (Public Law 112-144, Title III) was signed into law by the President on July 9, 2012. GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA enables FDA to assess user fees to support critical and measurable enhancements to FDA's generic drugs program.

GDUFA establishes fees for abbreviated new drug applications (ANDAs), prior approval supplements (PASs) to ANDAs, and drug master files (DMFs), annual facility fees, and a one-time fee for original ANDAs pending with FDA on October 1, 2012 (backlog fees). Fees are incurred for ANDAs and PASs submitted on or after October 1, 2012. An application fee is also incurred the first time a DMF is referenced in an ANDA or PAS submitted on or after October 1,

2012. FDA previously announced GDUFA fees for fiscal year 2013 in the Federal Register. ANDA, PAS, and DMF fees were published on October 25, 2012 (77 FR 65198); the backlog fee was published on October 25, 2012 (77 FR 65199); and facility fees were published on January 17, 2013 (78 FR 3900). GDUFA fees for fiscal year 2014 were announced in the Federal Register of August 2, 2013 (78 FR 46977).

On August 27, 2012, FDA announced the availability of a draft guidance for industry entitled "Generic Drug User Fee Amendments of 2012: Questions and Answers" (77 FR 51814). The comment period on the draft guidance closed on October 26, 2012. In response to comments received in the docket and to address additional questions that have arisen since the launch of the GDUFA program, FDA has revised the draft guidance and is issuing it again in draft to solicit public comment. Revision 1 clarifies some of the questions and answers in the first version and adds several new questions and answers. The questions and answers address four key categories: Fees; self-identification of facilities, sites, and organizations; review of generic drug submissions; and inspections and compliance.

This revised 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 "Generic Drug User Fee Amendments of 2012: Questions and Answers (Revision 1)." 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.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: September 2, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

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