4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Generic Drug User Fee Amendments of 2012: Questions and Answers Related to Self-Identification of Facilities, Review of Generic Drug Submissions, and Inspections and Compliance; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled "Generic Drug User Fee Amendments of 2012: Questions and Answers Related to Self-Identification of Facilities, Review of Generic Drug Submissions, and Inspections and Compliance." The Generic Drug User Fee Amendments of 2012 (GDUFA) are designed to speed the delivery of safe and effective generic drugs to the public and to improve the review process for abbreviated new drug applications (ANDAs). This guidance is intended to provide 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. This guidance finalizes the draft guidance originally issued in August 2012 and issued in revised draft form in September 2013.

DATES: Submit either electronic or written comments on this guidance at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2012-D-0880 for "Generic Drug User Fee Amendments of 2012: Questions and Answers Related to Self-

Identification of Facilities, Review of Generic Drug Submissions, and Inspections and Compliance." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket

number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Sonia Kim, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, 240-402-5118.

SUPPLEMENTARY INFORMATION:

I. Background

GDUFA (Pub. L. 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 to improve the review process for ANDAs. GDUFA enables FDA to assess user fees to support critical and measurable enhancements to FDA's generic drugs program.

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). On September 10, 2013, FDA announced the availability of a revised version of this guidance (78 FR 55261). The comment period on the revised draft guidance ended on December 11, 2013 (78 FR 70953). FDA received several comments on the draft guidance, and these comments as well as FDA's experience implementing GDUFA were considered as the guidance was finalized.

This guidance is intended to provide answers to common questions from generic drug industry participants and other interested parties involved in the development and/or testing of generic drug products regarding FDA's implementation of GDUFA. This guidance includes three categories of questions and answers: Self-identification of facilities, sites, and organizations; review of generic drug submissions; and inspections and compliance. The draft versions of this guidance also addressed the subject of fees. The portion of the draft guidance relating to fees was updated and finalized in November 2016 (81 FR 81774, November 18, 2016).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Generic Drug User Fee Amendments of 2012: Questions and Answers Related to Self- Identification of Facilities, Review of Generic Drug Submissions, and Inspections and Compliance." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

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

Dated: July 20, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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