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 User Fee Assessments; 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 guidance for industry entitled "Generic Drug User Fee Amendments of 2012: Questions and Answers Related to User Fee Assessments." This guidance provides 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 GDUFA user fees and finalizes the revised version of the guidance.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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 User Fee Assessments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 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: Mehrban Iranshad, Division of User Fee Management and Budget Formulation staff, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., rm. 4145, Silver Spring, MD 20993, 301-796-7900, AskGDUFA@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Generic Drug User Fee Amendments of 2012: Questions and Answers Related to User Fee Assessments." 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 improve upon the predictability of the review process. 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 2017 in the Federal Register. ANDA, PAS, DMF, and facility fees were published on July 27, 2016 (81 FR 49225), and the backlog fee was published on October 25, 2012 (77 FR 65199). 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). In response to comments received in the docket and to address additional questions that have arisen since the launch of the GDUFA program, FDA revised the draft guidance and re-issued it as "Draft Guidance for Industry on Generic Drug User Fee Amendments of 2012: Questions and Answers (Revision 1)" on September 10, 2013 (78 FR 55261). The guidance announced in this notice finalizes the section of Revision 1 relating to user fees, updating and clarifying the responses in some cases and adding questions and answers based on comments received from the public. Questions and answers related to GDUFA's self-identification, review of generic drug submissions, and inspections and compliance provisions that appeared in draft versions of this guidance will appear in updated form in a separately issued final guidance.

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 "Generic Drug User Fee Amendments of 2012: Questions and Answers Related to User Fee Assessments." 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.

II. Electronic Access

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

Dated: November 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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