

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 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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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Draft Guidance for Industry on Generic Drug User Fee Amendments of 2012: Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Generic Drug User Fee Amendments of 2012: Questions and Answers.” 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 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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 26, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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, 10903 New Hampshire Ave., Silver Spring, MD 20993, 866-405-5367 or 301-796-6707.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Generic Drug User Fee Amendments of 2012: Questions and Answers.” 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 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 will be incurred for ANDAs and PASs submitted on or after October 1, 2012. An application fee will also be incurred the first time a DMF is referenced in an ANDA or PAS submitted on or after October 1, 2012. FDA plans to publish the fee amounts for ANDAs, PASs, DMFs, and the backlog fee in the **Federal Register** on or before October 31, 2012.

The amount of the annual user fees for generic drug facilities will be determined after GDUFA program launch. Under GDUFA, facilities, sites, and organizations are first required to self-identify. Fees will be determined after the self-identification process has been completed, providing FDA information about the number of facilities that will be required to pay user fees. These include facilities manufacturing, or intending to manufacture, active pharmaceutical ingredients of human generic drugs and/or finished dosage form human generic drugs.

This draft 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 plans for implementing GDUFA. 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 generic drug user fee amendments of 2012. 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 written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to <http://www.regulations.gov>. 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: August 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0882]

Generic Drug User Fee Amendments of 2012; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a

public meeting to discuss implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA). GDUFA requires that generic drug manufacturers pay user fees to finance critical and measurable generic drug program enhancements and also requires that generic drug facilities, sites, and organizations around the world provide identification information annually to FDA. The purpose of the public meeting is to discuss recent communications concerning GDUFA implementation and to provide an opportunity for the public to present views on these materials.

DATES: The public meeting will be held on September 21, 2012, from 9 a.m. to 1 p.m.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 2, Rm. 2047, Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT:

Mary Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6178, Silver Spring, MD 20993, 301-796-3519, email: Mary.Gross@fda.hhs.gov; or Randi Clark, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6166, Silver Spring, MD 20993, 301-796-4287, email: Randi.Clark@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Comments: Submission of comments before the meeting is strongly encouraged. Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments. Submit electronic comments 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. 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. The deadline for submitting comments is October 12, 2012.

Attendance and Registration: If you wish to attend and/or present at the meeting, please register for the meeting and/or make a request for oral presentation by email to GDUFA_Meeting@fda.hhs.gov by September 14, 2012. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. (FDA may limit the number of participants from each organization, as well as the total number of participants, based on space limitations.) Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on the availability of space.

We will try to accommodate all persons who wish to make a presentation. Those making oral presentations at the meeting should submit to the docket a brief summary of the presentation (or questions), including the discussion topic(s) that will be addressed and the approximate time requested for your presentation. The time allotted for presentations will depend on the number of persons who wish to speak. If you need special accommodations because of a disability, please contact Mary Gross or Randi Clark (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

For those unable to attend in person, FDA will provide a Webcast and a telephone audio link to the meeting. To join the meeting via the Webcast, please go to <https://collaboration.fda.gov/gdufa91012>. If you have never attended a Connect Pro meeting, you may wish to test your connection by going to https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.

I. Background

On July 9, 2012, GDUFA (Pub. L. 112-144, Title III) was signed into law by the President. Designed to speed access to safe and effective generic drugs to the public and reduce costs to industry, GDUFA requires that generic drug manufacturers pay user fees to finance critical and measurable generic drug program enhancements. GDUFA also requires that generic drug facilities, sites, and organizations located around the world provide identification information annually to FDA. Additional information concerning GDUFA, including the text of the law and the letter in which FDA describes commitments it is making for improvements in the process, may be

found on the FDA Web site at <http://www.fda.gov/gdufa>.

The purpose of this meeting is to discuss recent communications that provide greater detail on FDA's GDUFA implementation plans. These communications are published elsewhere in this issue of the **Federal Register** and include the following:

- Draft Guidance for Industry *Generic Drug User Fee Amendments of 2012: Questions and Answers* (available at <http://www.fda.gov/gdufa>)
- Draft Guidance for Industry *Self-Identification of Generic Drug Facilities, Sites, and Organizations* (available at <http://www.fda.gov/gdufa>)
- **Federal Register** Notice of Opportunity To Withdraw Abbreviated New Drug Applications To Avoid Backlog Fee Obligations (available at <http://www.fda.gov/gdufa>)

The meeting will provide an overview of these communications and an opportunity for public input.

II. Meeting Organization

In general, the meeting format will include presentations by FDA, a panel discussion with stakeholder groups, individual public testimony, and an opportunity for questions and answers from the audience. The amount of time available for public testimony will be determined by the number of people who register to provide testimony. An agenda and other background for the public meeting will be posted at <http://www.fda.gov/gdufa> at least 2 days in advance of the meeting.

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated August 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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