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.

[FR Doc. 2012–20946 Filed 8–22–12; 11:15 am]

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Draft Guidance for Industry on Generic Drug User Fee Amendments of 2012: Questions and Answers; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Generic Drug User Fee Amendments of 2012: Questions and Answers.''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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 26, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201,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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*.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