



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 (Public Law 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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