



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2013-N-0402]

Generic Drug User Fee Amendments of 2012; Regulatory Science Initiatives; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a public hearing that will provide an overview of the current status of regulatory science initiatives for generic drugs and an opportunity for public input on research priorities in this area. FDA is seeking this input from a variety of stakeholders--industry, academia, patient advocates, professional societies, and other interested parties--as it fulfills its commitment under the Generic Drug User Fee Amendments of 2012 (GDUFA) to develop an annual list of regulatory science initiatives specific to generic drugs. FDA will take the information it obtains from the public hearing into account in developing the fiscal year (FY) 2017 Regulatory Science Plan.

DATES: The public hearing will be held on May 20, 2016, from 9 a.m. to 5 p.m. The public hearing may be extended or may end early depending on the level of public participation.

ADDRESSES: The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public hearing 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>.

Comments: 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-2013-N-0402 for "Generic Drug User Fee Amendments of 2012; Regulatory Science Initiatives; Public Hearing; Request for Comments." 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.

FOR FURTHER INFORMATION CONTACT: Thushi Amini, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 4728, Silver Spring, MD 20993, 240-402-7958, email: Thushi.Amini@fda.hhs.gov; or Robert Lionberger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 4722, Silver Spring, MD 20993, 240-402-7957, email: Robert.Lionberger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In July 2012, Congress passed GDUFA (Title III of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144)). GDUFA is designed to enhance public access to safe, high-quality generic drugs and modernize the generic drug program. To support this goal,

FDA agreed in the GDUFA commitment letter to work with industry and interested stakeholders on identifying regulatory science research priorities specific to generic drugs for each fiscal year covered by GDUFA. The commitment letter outlines FDA's performance goals and procedures under the GDUFA program for the years 2012-2017. The commitment letter can be found at <http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf>.

II. Purpose and Scope of the Public Hearing

The purpose of the May public hearing is to obtain input from industry and other interested stakeholders on the identification of regulatory science priorities for FY 2017. To help fulfill FDA's mission, FDA is particularly interested in receiving input on the following topics:

1. Opportunities for scientific or technical advancements that would help to overcome specific barriers for industry that currently limit the availability of generic drug products.
2. Innovative approaches to pre-approval development of generic drugs, including new methodologies for product design and manufacturing, and design and conduct of in vitro, ex vivo, and clinical studies and identification of scientifically robust strategies for demonstration of bioequivalence for various product classes.
3. Innovation in scientific approaches to evaluating the therapeutic equivalence of generic drug products throughout their lifecycle.
4. Identification of high-impact public health issues involving generic drugs that can be addressed by the prioritized allocation of FY 2017 funding for regulatory science research.
5. Identification of specific issues related to generic drug products where scientific recommendations and/or clarifications are needed in developing and/or revising FDA's guidance for industry.

6. Strategies for enhancing quality and equivalence risk management during generic drug product development, during regulatory review, and/or throughout the drug product's lifecycle.

FDA will consider all comments made at this hearing or received through the docket (see ADDRESSES) as it develops its FY 2017 GDUFA Regulatory Science Plan. Additional information concerning GDUFA, including the text of the law and the commitment letter, can be found at <http://www.fda.gov/gdufa>.

Registration and Requests for Oral Presentations: The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance will be free and on a first-come, first-served basis. If you wish to attend (either in person or by Webcast (see Streaming Webcast of the Public Hearing)) and/or present at the hearing, please register for the hearing and/or make a request for oral presentations or comments by email to GDUFARegulatoryScience@fda.hhs.gov by April 29, 2016. The email should contain complete contact information for each attendee (i.e., name, title, affiliation, address, email address, and telephone number). Those without email access can register by contacting Thushi Amini by April 29, 2016 (see FOR FURTHER INFORMATION CONTACT).

FDA will try to accommodate all persons who wish to make a presentation. Individuals wishing to present should identify the number of the topic, or topics, they wish to address. This will help FDA organize the presentations. FDA will notify registered presenters of their scheduled presentation times. The time allotted for each presentation will depend on the number of individuals who wish to speak. Once FDA notifies registered presenters of their scheduled times, they are encouraged to submit an electronic copy of their presentation to GDUFARegulatoryScience@fda.hhs.gov on or before May 6, 2016. Persons registered to make

an oral presentation are encouraged to arrive at the hearing room early and check in at the onsite registration table to confirm their designated presentation time. An agenda for the hearing and other background materials will be made available 5 days before the hearing at <http://www.fda.gov/GDUFARegScience>.

If you need special accommodations because of a disability, please contact Thushi Amini (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the hearing.

Streaming Webcast of the Public Hearing: For those unable to attend in person, FDA will provide a live Webcast of the hearing. To join the hearing via the Webcast, please go to <https://collaboration.fda.gov/r7qyz2eds95>.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov> or at <http://www.fda.gov/GDUFARegScience>. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <http://www.fda.gov>.

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with 21 CFR part 15. The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner and the Center for Drug Evaluation and Research. Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may pose questions; they may question any person during or at the conclusion of each presentation. Public hearings under part

15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C). Under § 10.205, representatives of the media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see Transcripts). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

Dated: March 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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