4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled "Generic Drug User Fee Amendments of 2012; Regulatory Science Initiatives." The topics to be discussed 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 workshop into account in developing the fiscal year (FY) 2018 Regulatory Science Plan.

DATES: The public workshop will be held on May 3, 2017, from 8:30 a.m. to 4:30 p.m. The registration deadline to attend either in person, or virtually via web cast, is April 5, 2017. Comments regarding this public workshop may be submitted March 2, 2017, through June 2, 2017.

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

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://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 https://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 Workshop; Request for Comments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://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 https://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 https://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: Stephanie Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 75, rm. 4736, Silver Spring, MD 20993, 240-402-7960, Stephanie.Choi@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, 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. Topics for Discussion at the Public Workshop

The purpose of the May public workshop is to obtain input from industry and other interested stakeholders on the identification of generic drug regulatory science priorities for FY 2018. FDA is holding this public workshop because the Agency intends to continue its regulatory science initiatives upon reauthorization of GDUFA (i.e., GDUFA II) for FYs 2018-2022 (see Generic Drug User Fees; Public Meeting; Request for Comments, 81 FR 66035, September 26, 2016). To help fulfill its mission, FDA is particularly interested in receiving input on the following topics:

- Opportunities for scientific or technical advancements that would help to overcome specific barriers for industry that currently limit the availability of generic drug products.
- 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.

- Innovation in scientific approaches to evaluating the therapeutic equivalence of generic drug products throughout their life cycle.
- Identification of high-impact public health issues involving generic drugs that can be addressed by the prioritized allocation of FY 2018 funding for regulatory science research.
- 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.
- Strategies for enhancing quality and equivalence risk management during generic drug product development, during regulatory review, and/or throughout the drug product's life cycle.

FDA will consider all comments made at this workshop or received through the docket (see ADDRESSES) as it develops its FY 2018 regulatory science priorities. Additional information concerning GDUFA, including the text of the law and the commitment letter, can be found at http://www.fda.gov/gdufa.

III. Participating in the Public Workshop

Registration: To register to attend "Generic Drug User Fee Amendments of 2012; Regulatory Science Initiatives; Public Workshop" in-person, or to attend virtually via web cast, please send an email to GDUFARegulatoryScience@fda.hhs.gov by April 5, 2017. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Any person without email access can register by contacting

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

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by April 5, 2017, midnight eastern standard time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the public comment session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by April 19, 2017. All requests to make oral presentations must be received by the close of registration on April 5, 2017, midnight eastern standard time. If selected for presentation, any presentation materials must be emailed to GDUFARegulatoryScience@fda.hhs.gov no later than April 26, 2017. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be web cast. To join via the web cast, please go to https://collaboration.fda.gov/gpw517/. Please register in advance for web cast per the instructions provided in this section.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview. FDA has verified the web site addresses in this document, as of the date this document publishes in the Federal Register, but web sites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Division of Dockets Management (see ADDRESSES). A link to the transcript will also be available on the Internet at http://www.fda.gov/GDUFARegScience.

Dated: March 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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