Dated: April 15, 2015.

Leslie Kux,

Associate 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 Fees; 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 on the Generic Drug User Fee Amendments of 2012 (GDUFA). The legislative authority for GDUFA expires at the end of September 2017. At that time, new legislation will be required for FDA to continue to collect generic drug user fees for future fiscal years. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that before FDA begins negotiations with the regulated industry on GDUFA reauthorization; we publish a notice in the **Federal Register** requesting public input on the reauthorization, hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in the Generic Drug User Fee Act Program Performance Goals and Procedures (*i.e.,* the Commitment Letter), provide a period of 30 days after the public meeting to obtain written comments from the public, and publish the comments on FDA's Web site. FDA invites public comment on the GDUFA program and suggestions regarding the features FDA should propose for the next GDUFA program.

DATES: The public meeting will be held on June 15, 2015, from 9 a.m. to 5 p.m. The public meeting may be extended or may end early depending on the level of public participation.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. 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, refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Connie Wisner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1718, Silver Spring, MD 20993, 240–402–7946, *Connie.Wisner@fda.hhs.gov;* or Kimberly Giordano, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1611, Silver Spring, MD 20993, 301–796–1071, *Kimberly.Giordano@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act, which included GDUFA (Pub. L. 112–144, title III), was signed into law by the President. GDUFA authorizes FDA to collect fees from drug companies that submit marketing applications for certain generic human drug applications, certain drug master files, and certain facilities. Designed to speed access to safe and effective generic drugs to the public, 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 around the world provide identification information annually to FDA.

Additional information concerning GDUFA, including the text of the law, the Commitment Letter, key **Federal Register** documents, GDUFA-related guidances, performance reports, and financial reports may be found on the FDA Web site at *http://www.fda.gov/gdufa.*

II. Purpose of Public Meeting

FDA is announcing a public meeting on GDUFA. The authority for GDUFA expires at the end of September 2017. Without new legislation, FDA will no longer be able to collect user fees to fund the human generic drug review process. Section 744(C)(d)(2) (21 U.S.C. 379j–43(d)(2)) of the FD&C Act requires that before FDA begins negotiations with the regulated industry on GDUFA reauthorization, we do the following: (1) Publish a notice in the **Federal Register** requesting public input on the reauthorization, (2) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in the Commitment Letter, (3) provide a period of 30 days after the public meeting to obtain written comments from the public, and (4) publish the comments on the FDA Web site. This notice, the public meeting, the 30-day comment period after the meeting, and the posting of the comments on the FDA Web site will satisfy these requirements. The purpose of the public meeting is to receive public input on the reauthorization of GDUFA, including specific suggestions for changes to the goals referred to in the Commitment Letter. FDA is interested in responses to the following two general questions and welcomes any other relevant information the public would like to share:

- What is your assessment of the overall performance of the GDUFA program to date?
- What aspects of GDUFA should be retained, changed, or discontinued to further strengthen and improve the program?

In general, the meeting format will include presentations by FDA, scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, the generic drug industry, and the general public. The amount of time available for public testimony will be determined by the number of persons who register to present at the meeting. A draft agenda and other background information for the public meeting will be posted at *http://www.fda.gov/gdufa* by June 8, 2015.

III. Meeting Attendance and Participation

FDA is seeking participation (*i.e.,* attendance and oral presentations) at the public meeting by all interested parties, including but not limited to scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, the generic drug industry, and the general public. If you wish to attend the meeting, please email your registration information to *GenericDrugPolicy@fda.hhs.gov* by June 1, 2015. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free and is on a first-come, first-served basis. Early registration is recommended because seating is limited. Registrants will receive confirmation once they have been accepted. If registration becomes full prior to the meeting, FDA will place a notice on *http://www.fda.gov/gdufa.* Onsite registration on the day of the

meeting will be based on space availability.

If you wish to present at the meeting, please include your presentation materials along with your registration information to *GenericDrugPolicy@fda.hhs.gov* by June 1, 2015. Early requests for oral presentations are recommended due to possible space and time limitations. FDA will accommodate as many requests for oral presentations as possible and will do so on a first-come, first-served basis. The time allotted for presentations may depend on the number of persons who wish to speak. Those requesting to present will receive confirmation once they have been accepted. If presentations exceed time and space limitations prior to the meeting, FDA will place a notice on *http://www.fda.gov/gdufa.* Onsite requests for oral presentations on the day of the meeting will be based on time and space availability. If the entire meeting time is not needed, FDA may end the public meeting early.

If you need special accommodations because of a disability, please contact Connie Wisner or Kimberly Giordano (see **FOR FURTHER INFORMATION CONTACT**) by June 8, 2015.

For those unable to attend in person, FDA will provide a live Adobe Connect Webcast of the meeting. In order to connect to the Webcast, you must have Adobe Connect. To join the meeting via the Adobe Connect Webcast, please go to: *https://collaboration.fda.gov/gdufaii.*

IV. Comments

Regardless of participation at the public meeting, interested persons may submit either electronic or written comments regarding this document. To ensure consideration, all comments should be received by July 15, 2015. Submission of comments prior to the meeting is strongly encouraged.

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. Identify all comments with the docket number found in the 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.

V. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov* and *http://www.fda.gov/gdufa.* It may be viewed at the Division of Dockets Management (see section IV). A transcript also will be available in either hard copy or on CD–ROM upon submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: April 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0975]

Acceptance of Medical Device Clinical Data From Studies Conducted Outside the United States; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Acceptance of Medical Device Clinical Data from Studies Conducted Outside the United States; Draft Guidance for Industry and Food and Drug Administration Staff.'' This draft guidance articulates FDA's current policy of accepting scientifically valid clinical data obtained from foreign clinical studies in support of premarket submissions for devices. The guidance describes special considerations that apply when using such data, including applicability to populations within the United States and study design issues and provides recommendations to assist sponsors in ensuring their data are adequate under applicable FDA standards to support approval or clearance of the device in the United States. This guidance is not intended to announce new policy, but to describe FDA's existing approach to this topic. This draft guidance is not final nor is it in effect at this time.

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 July 20, 2015.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Acceptance of Medical Device Clinical Data from Studies Conducted Outside the United States; Draft Guidance for Industry and Food and Drug Administration Staff'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 71, Rm. 3128, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request.

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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Aaliyah Eaves-Leaños, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5420, Silver Spring, MD 20993–0002, 301–796–2948. For questions regarding this document concerning devices regulated by CBER, contact Stephen Ripley, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA), Public Law 112–144 (2012), adding a new provision, section 569B, to the Federal Food, Drug, and Cosmetic Act (FD&C Act) codifying FDA's longstanding policy of accepting adequate, ethically-derived, scientifically valid data without regard to where a clinical study is conducted. Sponsors may choose to conduct multinational clinical studies under a variety of scenarios. FDA acknowledges, however, that certain challenges exist in using data derived from studies of devices from sites from outside the United States (OUS) to support an FDA