4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0882]

Generic Drug User Fees; Stakeholder Meetings on Generic Drug User Fee Amendments of 2012 Reauthorization; Request for Notification of Stakeholder Intent to Participate; Extension of Closing Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of intent to participate; extension of closing date.

SUMMARY: The Food and Drug Administration (FDA) is extending the closing date for the document that appeared in the Federal Register of June 3, 2015. In that document, FDA requested that public stakeholders, including patient and consumer advocacy groups, health care professionals, and scientific and academic experts, notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Generic Drug User Fee Amendments of 2012 (GDUFA). The statutory authority for GDUFA expires at the end of September 2017. At that time, new legislation will be required for FDA to continue collecting user fees for the generic drug program. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next GDUFA program. The FD&C Act also requires that FDA hold continued discussions with patient and consumer advocacy groups at least monthly during FDA's negotiations with the regulated

industry. The purpose of the request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent stakeholder representation.

DATES: FDA is extending the closing date in the notice published June 3, 2015 (80 FR 31602). Submit notification of intent to participate by April 30, 2016.

ADDRESSES: Submit notification of intent to participate in monthly stakeholder meetings by email to GenericDrugPolicy@fda.hhs.gov.

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 20993-0002, 240-402-7946, Connie.Wisner@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is requesting that public stakeholders, including patient and consumer advocacy groups, health care professionals, and scientific and academic experts, notify the Agency of their intent to participate in periodic consultation meetings on the reauthorization of GDUFA. 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. GDUFA requires that generic drug manufacturers pay user fees to finance critical and measurable generic drug program enhancements. The statutory authority for GDUFA expires at the end of September 2017. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the human generic drug review process. Section 744C(d) (21 U.S.C. 379j-43(d)) of the FD&C Act requires that FDA consult with a range of stakeholders in developing recommendations for the next GDUFA program, including representatives from patient and consumer groups, health care professionals, and scientific and academic experts.

FDA initiated this process on June 15, 2015, by holding a public meeting at which stakeholders and other members of the public were given an opportunity to present their views on reauthorization (April 21, 2015, 80 FR 22204). The FD&C Act further requires that FDA continue meeting with these stakeholders at least once every month during negotiations with the regulated industry to continue discussions of stakeholder views on the reauthorization.

FDA is issuing this Federal Register notice to request that stakeholder representatives from patient and consumer groups, health care professional associations, as well as scientific and academic experts notify FDA of their intent to participate in periodic consultation meetings on GDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensuring progress in these discussions. If you wish to participate in this part of the reauthorization process, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions as needed. Stakeholders who identify themselves through this notice will be included in all stakeholder discussions while FDA negotiates with the regulated industry. Stakeholders who decide to participate in these monthly meetings at a later time may still participate in remaining monthly meetings by notifying FDA (see ADDRESSES). These stakeholder discussions will satisfy the requirement in section 744C(d)(3) of the FD&C Act.

II. Notification of Intent to Participate in Periodic Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding GDUFA reauthorization, please provide notification by email to GenericDrugPolicy@fda.hhs.gov by April 30, 2016. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive

confirmation and additional information about the first meeting once FDA receives their notification.

Dated: August 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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