4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2020-N-1861]**

# Generic Drug User Fees; Stakeholder Meetings on Generic Drug User Fee Amendments of 2017 Reauthorization; Request for Notification of Stakeholder Intention To Participate

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice; request for notification of participation.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is issuing this notice to request that public stakeholders, including patient and consumer advocacy groups, healthcare 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 2017 (GDUFA). At the end of September 2022, new legislation will be required for FDA to continue collecting generic drug user fees for subsequent fiscal years for the generic drug program. The Federal Food, Drug, and Cosmetic Act (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 this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent stakeholder representation.

**DATES:** Submit notification of intention to participate in these series of meetings by October 8, 2020. Stakeholder meetings will be held monthly, and it is anticipated that they will commence in October 2020.

**ADDRESSES:** The meetings will take place virtually and will be held by webcast only. Submit notification of intention to participate in monthly stakeholder meetings by email to GenericDrugPolicy@fda.hhs.gov. See the SUPPLEMENTARY INFORMATION section for registration date and information.

**FOR FURTHER INFORMATION CONTACT:** Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993, 240-402-8926, Dat.Doan@fda.hhs.gov; or Tiana Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6196, Silver Spring, MD 20993, 301-796-2882, Tiana.Barnes@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is requesting that public stakeholders, including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts, notify the Agency of their intent to participate in periodic stakeholder consultation meetings on the reauthorization of GDUFA. GDUFA authorizes FDA to collect user fees from the regulated industry for the current program (GDUFA II). At the end of September 2022, new legislation will be required for FDA to continue collecting user fees for subsequent fiscal years for the generic drug program. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund human generic drug activities. Section 744C(f) (21 U.S.C. 379j-43(f)) 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, healthcare professionals, and scientific and academic experts. FDA initiated this process by holding a public meeting on July 21, 2020, at which stakeholders and other

members of the public were given an opportunity to present their views on reauthorization (85 FR 38378). 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. It is anticipated that these monthly stakeholder consultation meetings will commence in October 2020.

FDA is issuing this *Federal Register* notice to request that stakeholder representatives from patient and consumer groups, healthcare professional associations, as well as scientific and academic experts notify FDA of their intent to participate in periodic stakeholder consultation meetings on GDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensure progress in these discussions. If you wish to participate in the stakeholder consultation meetings, 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 consultation requirement in section 744C(f)(3) (21 U.S.C. 379j-43(f)(3)) of the FD&C Act.

II. Notification of Intent To Participate in Periodic Stakeholder 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 October 8, 2020. 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 after FDA receives this notification. Information concerning GDUFA, including the text of the law, the GDUFA II Commitment Letter, key *Federal Register* documents, GDUFA-related guidances, performance reports, and financial reports may be found on the FDA website at https://www.fda.gov/gdufa.

Dated: September 10, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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