



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2253]

Medical Device User Fees; Stakeholder Meetings on Medical Device User Fee Amendments of Fiscal Years 2023 to 2027 Reauthorization; Request for Notification of Stakeholder Intention to Participate

AGENCY: Food and Drug Administration, 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 Medical Device User Fee Amendments (MDUFA). The statutory authority for MDUFA expires in September 2022. At that time, new legislation will be required for FDA to continue collecting user fees for the medical device 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 MDUFA program. The FD&C Act also requires that FDA hold discussions (at least every month) with patient and consumer advocacy groups 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 public stakeholder representation.

DATES: Submit notification of intention to participate in these series of meetings by February 26, 2021. Stakeholder meetings will be held monthly. It is anticipated that they will commence in March 2021. See the SUPPLEMENTARY INFORMATION section for registration date and information.

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 MDUFAVReauthorization@fda.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Ellen Olson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1664, Silver Spring, MD 20993, 301-796-4322, MDUFAVReauthorization@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 MDUFA. MDUFA authorizes FDA to collect user fees from the regulated industry for the process for the review of medical devices. The authorization for the current program (MDUFA IV) expires in September 2022. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the medical device review process.

Section 738A(b)(1) of the FD&C Act (21 U.S.C. 379j-1(b)(1)) requires that FDA consult with a range of stakeholders, including representatives from patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts, in developing recommendations for the next MDUFA program. FDA initiated the reauthorization process by holding a public meeting on October 27, 2020, where stakeholders and other members of the public were given an opportunity to present their views on the reauthorization. The FD&C Act further requires that FDA continue meeting with the representatives of patient and consumer advocacy groups at least once every month during negotiations with the regulated industry to continue discussions of stakeholder views on the reauthorization and their suggestions for changes. It is anticipated that these monthly stakeholder consultation meetings will commence in March 2021.

FDA is issuing this *Federal Register* notice to request that stakeholder representatives from patient and consumer advocacy groups, healthcare professional associations, as well as scientific and academic experts, notify FDA of their intent to participate in the periodic stakeholder consultation meetings on MDUFA 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. Stakeholders who identify themselves through this notice, and are otherwise eligible to attend, may participate in all stakeholder consultation discussions while FDA negotiates with the regulated industry. These stakeholder discussions will satisfy the consultation requirement in section 738A(b)(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 MDUFA reauthorization, please provide notification by email to MDUFVReauthorization@fda.hhs.gov by February 26, 2021. 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 from FDA after the Agency receives this notification.

Dated: February 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.