II. Request for Comments

FDA is soliciting comments on the ''Product Quality Information Request Communications Assessment: Final Report'' from interested parties. We request feedback on: (1) the assessment findings and recommendations, (2) whether certain recommendations are more desirable than others, and (3) other actions FDA and applicants should consider and why.

III. Electronic Access

Persons with access to the internet may obtain the report at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-assessment-fda-and-sponsor-communications-through-product-quality-information-requests.*

Dated: May 6, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0834]

Prescription Drug User Fee Act; Stakeholder Consultation Meetings on the Prescription Drug User Fee Act 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 Prescription Drug User Fee Act (PDUFA). The statutory authority for PDUFA expires in September 2027. At that time, new legislation will be required for FDA to continue collecting user fees for the prescription 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 PDUFA 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 stakeholder representation.

DATES: Submit notification of intention to participate in these series of meetings by August 4, 2025. Stakeholder meetings will be held monthly. It is anticipated that they will commence in September 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Submit notification of intention to participate in monthly stakeholder meetings by email to *PDUFAReauthorization@fda.hhs.gov.* The meetings will be held in person at the FDA White Oak campus, 10903 New Hampshire Ave., Silver Spring, MD 20993 and virtually using the Microsoft Teams platform.

FOR FURTHER INFORMATION CONTACT: Andrew Kish, Center for Drug Evaluation and Research, Food and Drug Administration, 301–796–5215, *Andrew.Kish@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 PDUFA. PDUFA authorizes FDA to collect user fees from the regulated industry for the process for the review of human drugs. The authorization for the current program (PDUFA VII) expires in September 2027. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the human drug review process.

Section 736B(f)(1) of the FD&C Act (21 U.S.C. 379h–2(f)(1)) requires that FDA consult with a range of stakeholders, including representatives from patient and consumer groups, healthcare professionals, and scientific and academic experts, in developing recommendations for the next PDUFA program. FDA will initiate the reauthorization process by holding a public meeting on July 14, 2025, where stakeholders and other members of the public will be given an opportunity to present their views on the reauthorization. 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 September 2025.

FDA is issuing this 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 the periodic stakeholder consultation meetings on PDUFA 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 will be included in all stakeholder consultation discussions while FDA negotiates with the regulated industry. If a stakeholder decides to participate in these monthly meetings at a later time, that stakeholder may join the remaining monthly stakeholder consultation meetings after notifying FDA of this intention (see **ADDRESSES**). These stakeholder discussions will satisfy the consultation requirement in section 736B(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 PDUFA reauthorization, please provide notification by email to *PDUFAReauthorization@fda.hhs.gov* by August 4, 2025. 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.

Dated: May 6, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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