



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0655]

Animal Generic Drug User Fee Act; Stakeholder Consultation Meetings on the Animal Generic Drug User Fee Act Reauthorization; Request for Notification of Stakeholder Intent to Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing this notice to request that public stakeholders notify FDA of their intent to participate in periodic consultation meetings on reauthorization of the Animal Generic Drug User Fee Act (AGDUFA). The statutory authority for AGDUFA expires September 30, 2028. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of stakeholders—including patient and consumer advocacy groups, veterinary professionals, and scientific and academic experts—in developing recommendations for the next AGDUFA program and hold discussions with these stakeholders at least once every 4 months during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure consistent stakeholder representation at the consultation meetings.

DATES: Submit notification of intent to participate in continued periodic stakeholder consultation meetings regarding AGDUFA reauthorization by June 1, 2026. These stakeholder meetings are expected to commence in June 2026 and will continue at least once every 4 months during reauthorization negotiations with the regulated industry. See the **SUPPLEMENTARY INFORMATION** section for further information regarding notification of intent to participate.

ADDRESSES: Submit notification of intent to participate in this series of meetings by June 1, 2026 to AGDUFAReauth@fda.hhs.gov. These meetings will be held in person at the FDA

Harvey W. Wiley Federal Building in College Park, MD, 5001 Campus Drive, College Park, MD 20740 and virtually using the Microsoft Teams platform.

FOR FURTHER INFORMATION CONTACT: Madeline Faunce, on detail to Office of Operations, Office of Finance, Budget, and Acquisitions, Food and Drug Administration, 301-796-3464, AGDUFAReauth@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

In 2023, Congress passed the Animal Generic Drug User Fee Amendments of 2023 (Pub. L. 118-15; AGDUFA IV). The authority for AGDUFA IV expires September 30, 2028. Without new legislation to reauthorize the program, FDA will no longer be able to collect user fees for future fiscal years to fund the generic new animal drug review process. Section 742(d)(1) of the FD&C Act (21 U.S.C. 379j-22(d)(1)) requires that FDA consult with a range of stakeholders in developing recommendations for consideration for the next AGDUFA program, including representatives from patient and consumer advocacy groups, veterinary professionals, and scientific and academic experts. To initiate this process of consultation, we announced in the federal register of April 17, 2026 (91 FR 20691) that a public meeting is to be held on May 27, 2026, where stakeholders and other members of the public will be given an opportunity to present their views on the reauthorization. The meeting and written comments submitted to the docket will provide critical input as the Agency prepares for reauthorization discussions. Section 742(d)(3) of the FD&C Act further requires that FDA continue meeting with these stakeholders at least once every 4 months during negotiations with the regulated industry to continue discussions of their views on the reauthorization, including suggested changes to the AGDUFA program.

FDA is issuing this Federal Register notice to request that stakeholders—including veterinary professionals, patient and consumer advocacy groups, as well as scientific and academic experts—notify FDA of their intent to participate in the periodic consultation meetings on

AGDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings is essential in the reauthorization process. 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. Stakeholders who identify themselves through this notice will be included in all future stakeholder discussions while FDA negotiates with the regulated industry. If a stakeholder decides to participate in these meetings at a later time, they may still participate in remaining meetings by notifying FDA (see **FOR FURTHER INFORMATION CONTACT**). These stakeholder discussions will satisfy the requirement in section 742(d)(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 AGDUFA reauthorization, please submit notification by email to: AGDUFAreauth@fda.hhs.gov by June 1, 2026. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, email address, telephone number, and notice of any special accommodations required due to a disability (e.g., Closed Captioning). Stakeholders will receive confirmation and additional information about the first meeting, and subsequent meetings when scheduled, after FDA receives this notification of intent to participate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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