

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 740A(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 ADUFA reauthorization, please submit notification by email to: [ADUFAreauth@fda.hhs.gov](mailto:ADUFAreauth@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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## 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](mailto: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](mailto: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](mailto: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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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2022–D–1261]

**Clostridioides Difficile Infection: Developing Drugs for Treatment, Reduction of Recurrence, or Prevention; Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry titled “*Clostridioides difficile* Infection: Developing Drugs for Treatment, Reduction of Recurrence, or Prevention.” The purpose of this guidance is to assist sponsors in the clinical development of drugs to support an indication of treatment, reduction of recurrence, or prevention of *Clostridioides difficile* infection (CDI). This guidance finalizes the draft guidance titled “*Clostridioides difficile* Infection: Developing Drugs for Treatment, Reduction of Recurrence, and Prevention” issued on October 28, 2022.

**DATES:** The announcement of the guidance is published in the **Federal Register** on May 11, 2026.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

**Electronic Submissions**

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any

confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA–2022–D–1261 for “*Clostridioides difficile* Infection: Developing Drugs for Treatment, Reduction of Recurrence, or Prevention.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly

available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Ramya Gopinath, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 22, Rm. 6150, Silver Spring, MD 20993, 240–402–5328.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry titled “*Clostridioides difficile* Infection: Developing Drugs for Treatment, Reduction of Recurrence, or Prevention.” The purpose of this guidance is to assist sponsors in the clinical development of drugs to support an indication of treatment, reduction of recurrence, or prevention of CDI.

This guidance finalizes the draft guidance titled “*Clostridioides difficile* Infection: Developing Drugs for Treatment, Reduction of Recurrence, and Prevention” issued on October 28, 2022 (87 FR 65210). FDA did not receive public comments on the draft