4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-3708]

ADUFA V Third-Party Assessment Report: Notice of Availability; Virtual Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; announcement of virtual public meeting; and request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a report entitled "ADUFA V Third-Party Assessment Report" and a related virtual public meeting. The purpose of the virtual public meeting is to provide an overview of a third-party assessment that examines the implementation of the Animal Drug User Fee Act (ADUFA). FDA is soliciting comments on the assessment.

DATES: The virtual public meeting will be held on Thursday, October 30, 2025, at 10:00 AM (EST). Either electronic or written/paper comments on this public workshop must be submitted by December 30, 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: This public meeting is virtual only. Persons interested in attending this virtual public meeting must register at: https://events.gcc.teams.microsoft.com/event/0c499308-1f4e-49ef-8c23-a3d3b0712963@7d2fdb41-339c-4257-87f2-a665730b31fc. Additional details about the virtual public meeting are available on the ADUFA V Third-Party Assessment meeting webpage listed on the Center for Veterinary Medicine's "Workshops, Conferences and Meetings" page: https://www.fda.gov/animal-veterinary/news-events/workshops-conferences-meetings.

You may submit comments identified by Docket No. FDA-2025-N-3708 as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 30, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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-2025-N-3708 for "ADUFA V Third-Party Assessment Report." Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Petra Garosi, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240-402-0632, petra.garosi@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Animal Drug User Fee Act (Pub. L. 108-130) (ADUFA or the Act) was originally signed into law in 2003 and was subsequently reauthorized by Congress in 2008, 2013, 2018, and 2023. ADUFA authorizes FDA to collect fees for certain new animal drug applications, products, establishments, and sponsors. Resources generated under ADUFA supplement the Agency's funding to enhance the performance of the drug review process, ensuring that new animal drug products are safe and effective for animals, and that food derived from treated animals will be safe for consumption. FDA considers the timely review of the safety and effectiveness of new animal drug applications to be central to the Agency's mission to protect and promote human and animal health.

In 2023, during negotiations for the reauthorization of ADUFA, FDA’s Center for Veterinary Medicine (CVM) and stakeholders from the animal drug industry agreed that the Agency would engage an independent third-party to conduct a comprehensive assessment of the process for the review of animal drug applications. The assessment, completed in December 2024, evaluated the effectiveness of the ADUFA program, including the review process, the tools used to improve efficiency, and the allocation of available resources. The assessment consisted of stakeholder interviews with CVM and industry personnel, a comprehensive review of CVM system records and performance data, and an examination of the activities in the review process. This assessment examined user fee enhancements to the ADUFA program and animal

drug review process, and it assessed the effectiveness of these enhancements against their intended objectives and goals. The assessment was conducted from January 2024 – December 2024. The purpose of this virtual public meeting is to provide an overview of the results of the assessment.

II. Topics to be Presented at the Virtual Public Meeting

At the virtual public meeting, FDA will provide a general overview of the Third-Party Assessment. FDA is seeking input, via written comments to the docket referenced above, on all aspects of the third-party assessment. FDA encourages respondents to provide the specific rationale and basis for their comments, including any available supporting data and information. Respondents need not address all topics of the assessment.

III. Participating in the Virtual Public Meeting

Registration: Persons interested in attending this virtual public meeting must register online at https://events.gcc.teams.microsoft.com/event/0c499308-1f4e-49ef-8c23-a3d3b0712963@7d2fdb41-339c-4257-87f2-a665730b31fc. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

Registration is free but limited to 1000 participants. Persons interested in attending this virtual public meeting must register by 11:59 p.m. Eastern Time on October 29, 2025. Registrants will receive confirmation when they have been accepted. We will inform registrants if the limit of 1000 is reached, at which point we will no longer be able to accommodate additional participants.

Information on requesting special accommodations due to a disability will be provided during registration.

Notice of this meeting is given pursuant to 21 CFR 10.65.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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