

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Individual In-Depth Interview Screening	2,400	1	2,400	.08 (5 minutes)	192
Individual In-Depth Interviews	200	1	200	1	200
Focus Group/Small Group Participant Screening	5,400	1	5,400	.08 (5 minutes)	432
Focus Groups/Small Group Discussion	1,800	1	1,800	1.5	2,700
Observation Screening	720	1	720	.08 (5 minutes)	58
Observations	144	1	144	2	288
Total			10,664		3,870

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on both historical numbers of participants from past projects as well as estimates for projects to be conducted in the next 3 years. Based on a review of the information collection since our last request for OMB approval, we have adjusted our burden estimate based on actual usage of this collection of information and have decreased the number of responses and hours by half for these items, as listed in the first four rows in table 1. We have reduced our estimate for the number of responses from 19,600 to 9,800 responses (a decrease of 9,800 responses) and reduced the number of hours from 7,048 to 3,524 hours (a decrease of 3,524 hours) based on our experience conducting these collections of information. The total reduction in burden, therefore, is estimated as 9,800 responses and 3,524 hours. The new burden is estimated at 10,664 responses and 3,870 hours.

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-0656]

Animal Drug User Fee Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following virtual public meeting entitled “Animal Drug User Fee Act.” The purpose of the public meeting is to invite public comment on the Animal Drug User Fee Act (ADUFA) program and suggestions

regarding the features FDA should consider for the next reauthorization of the ADUFA program. The meeting will be open to the public.

DATES: The public meeting will be held virtually on May 27, 2026, from 2 p.m. to 4 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration dates and information. To permit the widest possible opportunity to obtain comments on all aspects of the public meeting, the docket will remain open for comment throughout the reauthorization process of ADUFA, until December 1, 2027. In addition to being publicly viewable at <http://www.regulations.gov>, comments received by July 1, 2026, suggesting changes to the program, will also be published on <https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings>.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 1, 2027. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 1, 2027. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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-2011-N-0656 for “Animal Drug User Fee Act.” Received comments, those filed in a timely manner, 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. A transcript of the public meeting will be made available in the docket, as well as on the FDA website at: <https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings>.

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, ADUFAReauth@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The authority for ADUFA expires September 30, 2028. Without new legislation, FDA will no longer have the authority to collect user fees to help fund the new animal drug review process for future fiscal years. Prior to beginning negotiations with the regulated industry on ADUFA reauthorization, section 740A(d)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379j-13(d)(2)) requires FDA to: (1) Publish a notice in the **Federal Register** requesting public input on the reauthorization; (2) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in

section 740A(a) of the FD&C Act; (3) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes; and (4) publish the comments on FDA’s website. This notice, the public meeting, the comment period after the meeting, and the posting of the comments on the FDA website will satisfy these requirements. FDA is holding a public meeting to gather information on what FDA should consider including in the reauthorization of ADUFA. FDA is interested in responses from the public on the following two general questions and welcomes other pertinent information that stakeholders would like to share:

1. What is your assessment of the overall performance of the ADUFA program thus far?
2. What aspects of ADUFA should be retained, changed, or discontinued to further strengthen and improve the program?

II. Background

FDA considers the timely review of new animal drug submissions to be central to the Agency’s mission to protect and promote human and animal health. The ADUFA program began in FY 2004 and is currently in the fifth authorization (ADUFA V). FDA has published a number of reports that provide useful background on ADUFA I, ADUFA II, ADUFA III, ADUFA IV and ADUFA V. ADUFA-related **Federal Register** notices, guidances, legislation, performance reports, and financial reports can be found at: <https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa>.

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register no later than midnight Eastern time on May 22, 2026, by emailing complete contact information for each attendee, including name, title, affiliation, address, email, telephone number, and if you need reasonable accommodations due to a disability (e.g., Closed Captioning) to ADUFAReauth@fda.hhs.gov. Registration is free and early registration is recommended. Registrants will receive confirmation when their registration has been received and will be provided the webcast link.

Requests for Oral Presentations: During online registration you may indicate if you wish to make an oral presentation during the public meeting. To facilitate agenda development, registrants requesting to present will be

asked to provide information regarding which topics they intend to address and the title of their presentation. We will do our best to accommodate requests to make an oral presentation. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate. All requests to make oral presentations must be received by May 1, 2026.

We will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and we will notify participants by May 8, 2026. Presenters planning to use an electronic slide deck must email an electronic copy of their presentation to Madeline Faunce at ADUFAReauth@fda.hhs.gov (see **FOR FURTHER INFORMATION CONTACT**) with the subject line “ADUFA Public Meeting Presentation” on or before May 15, 2026. If presenters choose not to use a slide deck, they are requested to email a single slide with their name, affiliation, title of their presentation, and contact information. No commercial or promotional material will be permitted to be presented at the public meeting.

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services.

ACTION: Notice.

Proposed Project: Evaluation of the Projects for Assistance in Transition From Homelessness (PATH) Program—Reinstatement

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, (SAMHSA will publish periodic summaries of proposed projects. To request more information on the