

[userfees.fda.gov/OA\\_HTML/omufaCAcdLogin.jsp](https://userfees.fda.gov/OA_HTML/omufaCAcdLogin.jsp).

A user fee identification (ID) number will be generated. Payment must be made in U.S. currency by electronic check or wire transfer, payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck).

FDA has partnered with the U.S. Department of the Treasury to use *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after completing the OTC Monograph User Fee Cover Sheet and generating the user fee ID number. Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. (Note: Only full payments are accepted through <https://userfees.fda.gov/pay>. No partial payments can be made online). Once an invoice is located, "Pay Now" should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than \$25,000 (Discover, VISA, MasterCard, American Express). If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied, which could result in FDA not filing an OMOR request, or other consequences of nonpayment. The originating financial institution may charge a wire transfer fee. Applicable wire transfer fees must be included with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53-0196965.

Dated: July 26, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024-16878 Filed 7-30-24; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2024-N-3029]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; FDA Food Safety and Nutrition Survey

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a collection of information used to conduct a voluntary consumer survey entitled, "FDA Food Safety and Nutrition Survey."

**DATES:** Either electronic or written comments on the collection of information must be submitted by September 30, 2024.

**ADDRESSES:** You may submit comments 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 September 30, 2024. 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-2024-N-3029 for "Agency Information Collection Activities; Proposed Collection; Comment Request; FDA Food Safety and Nutrition Survey." 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:** JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement

of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Food Safety and Nutrition Survey**

*OMB Control Number 0910-0345—Reinstatement*

Under section 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), we are authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation’s food supply. In the past, FDA has conducted two separate surveys, a Food Safety Survey and a Health and Diet Survey, to measure consumers’ knowledge, attitudes, and beliefs about food safety and nutrition issues. These surveys have been conducted every 3 to 5 years since the 1980s. In the **Federal Register** of August 14, 2018 (83 FR 40293), we announced the combination of these two surveys, which will now be the FDA Food Safety

and Nutrition Survey (FSANS). Data from FDA’s food safety and nutrition surveys have been used to support rulemaking and educational campaigns and to measure progress toward Healthy People 2010, 2020, and 2030 food safety goals. The proposed 2024 FSANS will contain many of the same questions and topics as the previous surveys to facilitate measuring trends in food safety and diet knowledge, attitudes, and behaviors over time. The proposed survey will also be updated to explore emerging consumer food safety and nutrition topics and to expand understanding of previously asked topics.

The 2024 FSANS will be both a paper-and-pencil and web-based survey. Respondents will be contacted by postal mail, using an addressed-based sampling frame. Once contacted, respondents will be encouraged to take the survey online. A paper-and-pencil version of the survey will be mailed to those who do not initially take the web-based version of the survey. One randomly selected adult from each sampled household will be invited to participate in the survey using the Hagen-Collier method.<sup>1</sup> A total of 5,000 respondents will be surveyed. We will sample approximately 25,000 households to offset nonresponding households and ineligible addresses and achieve 5,000 adult respondents. Participation in the survey will be voluntary. Cognitive interviews and a pre-test will be conducted prior to fielding the survey.

*Description of Respondents:* Respondents to this collection of information are individuals who are adults, age 18 and older, drawn from the 50 states and the District of Columbia.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive interview screener .....	75	1	75	0.083 (5 minutes) .....	6
Cognitive interview .....	18	1	18	1 .....	18
Pretest .....	100	1	100	0.33 (20 minutes) .....	33
Mail survey .....	5,000	1	5,000	0.33 (20 minutes) .....	1,650
<b>Total .....</b>			<b>5,193</b>		<b>1,707</b>

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

FDA’s burden estimate is based on the Agency’s prior experience with food

safety and nutrition surveys. We will use a cognitive interview screener with

75 individuals to recruit prospective interview participants for a total of 18

<sup>1</sup> In this method, we randomly select a category based on gender and age (based on the gender-age

composition of the household), and then take the adult in that selected category.

individuals. We estimate that it will take each screener respondent approximately 5 minutes (0.083 hours) to complete the cognitive interview screener, for a total of 6 hours. We will conduct cognitive interviews with 18 participants. We estimate that it will take each participant approximately 1 hour to complete the interview, for a total of 18 hours. Prior to the administration of the surveys, the Agency plans to conduct a pretest to identify and resolve potential survey administration problems. The pretest will be conducted with 100 participants; we estimate that it will take each participant 20 minutes (0.33 hours) for the pretest for a total of 33 hours. We estimate that 5,000 eligible adults will participate in the survey with each taking 20 minutes (0.33 hours), for a total of 1,650 hours. Thus, the total estimated burden is 1,707 hours.

Dated: July 26, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024-16832 Filed 7-30-24; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2024-N-3480]

#### Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2025

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2025 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Drug User Fee Amendments of 2023 (ADUFA V), authorizes FDA to collect user fees for certain animal drug applications and supplemental animal drug applications, for certain animal drug products, for certain establishments where such products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2025.

**DATES:** The application fee rates apply to applications submitted on or after October 1, 2024, and will remain in effect through September 30, 2025.

**FOR FURTHER INFORMATION CONTACT:** Visit FDA's website at: <https://www.fda.gov/>

*industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa* or contact Lisa Kable, Center for Veterinary Medicine (HFV-10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-6888, [Lisa.Kable@fda.hhs.gov](mailto:Lisa.Kable@fda.hhs.gov). For general questions, you may also email FDA's Center for Veterinary Medicine (CVM) at: [cvmadufa@fda.hhs.gov](mailto:cvmadufa@fda.hhs.gov).

*For questions relating to this notice:* Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240-402-4989; or the User Fee Support Staff at [OO-OFBAP-OFM-UFFS-Government@fda.hhs.gov](mailto:OO-OFBAP-OFM-UFFS-Government@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 740(a) of the FD&C Act (21 U.S.C. 379j-12), as amended by ADUFA V, establishes four different types of user fees: (1) fees for certain animal drug applications and supplemental animal drug applications; (2) annual fees for certain animal drug products; (3) annual fees for certain establishments where such products are made; and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions. When certain conditions are met, FDA will waive or reduce fees per section 740(d) of the FD&C Act.

For FYs 2024 through 2028, section 740(b)(1) of the FD&C Act establishes the base revenue amount for each fiscal year. Per section 740(c)(2) and (3) of the FD&C Act, the base revenue amounts established for fiscal years after FY 2024 are subject to adjustment for inflation and workload. Beginning in FY 2025, the annual fee revenue amount is also subject to an operating reserve adjustment to allow FDA to adjust the fee revenue amount to maintain a specified operating reserve of carryover user fees, per section 740(c)(4) of the FD&C Act. FDA may increase the fee revenue amount to maintain a 12-week minimum. If FDA has an excess operating reserve, FDA will decrease the fee revenue amount so that FDA has 22 weeks of operating reserve for FY 2025, 20 weeks for FY 2026, 18 weeks for FY 2027, and 16 weeks for FY 2028.

Per section 740(b)(2) of the FD&C Act, fees for applications, establishments, products, and sponsors are to be established each year by FDA so that the percentages of the total revenue that are derived from each type of user fee will be as follows: (1) revenue from application fees shall be 20 percent of total fee revenue; (2) revenue from product fees shall be 27 percent of total fee revenue; (3) revenue from

establishment fees shall be 26 percent of total fee revenue; and (4) revenue from sponsor fees shall be 27 percent of total fee revenue. The target revenue amounts for each fee category for FY 2025 are as follows: for application fees, the target revenue amount is \$5,701,000; for product fees, the target revenue amount is \$7,697,000; for establishment fees, the target revenue amount is \$7,412,000; and for sponsor fees, the target revenue amount is \$7,697,000.

For FY 2025, the animal drug user fee rates are: (1) \$581,735 for an animal drug application; (2) \$290,867 for a supplemental animal drug application for which safety or effectiveness data are required, for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b), and for an application for conditional approval under section 571 of the FD&C Act (21 U.S.C. 360ccc) for which an animal drug application submitted under section 512(b)(1) of the FD&C Act has been previously approved under section 512(d)(1) of the FD&C Act for another intended use; (3) \$10,705 for the annual product fee; \$157,702 for the annual establishment fee; and (4) \$137,446 for the annual sponsor fee. FDA will issue invoices for FY 2025 product, establishment, and sponsor fees by December 31, 2024, and payment will be due by January 31, 2025. The application fee rates are effective for applications submitted on or after October 1, 2024, and will remain in effect through September 30, 2025. Applications will not be accepted for review until FDA has received full payment of application fees and any other animal drug user fees owed under the ADUFA program.

##### II. Fee Revenue Amount for FY 2025

###### A. Statutory Fee Revenue Amounts

Section 740(b)(1) of the FD&C Act specifies that the base fee revenue amount for FY 2025 for all animal drug user fee categories totals \$33,500,000.

###### B. Inflation Adjustment to Fee Revenue Amount

Section 740(c)(2)(A)(ii) and (iii) of the FD&C Act specifies that the annual fee revenue amount is to be adjusted for inflation increases for FY 2025 and subsequent fiscal years using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs. Section 740(c)(2)(A)(ii) of the FD&C Act specifies the component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position (FTE) at FDA for the