encompassed by existing regulations or are consistent with voluntary standards which reflect industry's usual and customary business practice.

TABLE 7—COLLECTION OF INFORMATION REQUIRED BY CURRENT REGULATIONS AND STANDARDS

PHS guideline section	Description of collection of information activity	21 CFR section (unless otherwise stated)
2.2.1	Document off-site collaborations	312.52.
2.5	Sponsor ensures counseling patient + family + contacts	312.62(c).
3.1.1 and 3.1.6	Document well-characterized health history and lineage of source animals	312.23(a)(7)(a) and 211.84.
3.1.8	Registration with and import permit from the Centers for Disease Control and Prevention.	42 CFR 71.53.
3.2.2	Document collaboration with accredited microbiology labs	312.52.
3.2.3	Procedures to ensure the humane care of animals	9 CFR parts 1, 2, and 3 and PHS Policy.[1]
3.2.4	Procedures consistent for accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) and consistent with the National Research Council's (NRC) Guide.	AAALAC International Rules of Accreditation[2] and NRC Guide.[3]
3.2.5, 3.4, and 3.4.1	Herd health maintenance and surveillance to be documented, available, and in accordance with documented procedures; record standard veterinary care.	211.100 and 211.122.
3.2.6	Animal facility SOPs	PHS Policy[1].
3.3.3	Validate assay methods	211.160(a).
3.6.1	Procurement and processing of xenografts using documented aseptic conditions.	211.100 and 211.122.
3.6.2	Develop, implement, and enforce SOP's for procurement and screening processes.	211.84(d) and 211.122(c).
3.6.4	Communicate to FDA animal necropsy findings pertinent to health of recipient.	312.32(c).
3.7.1	PHS specimens to be linked to health records; provide to FDA justification for types of tissues, cells, and plasma, and quantities of plasma and leukocytes collected.	312.23(a)(6).
4.1.1	Surveillance of xenotransplant recipient; sponsor ensures documentation of surveillance program life-long (justify >2 yrs.); investigator case histories (2 yrs. after investigation is discontinued).	312.23(a)(6)(iii)(f) and (g), and 312.62(b) and (c).
4.1.2	Sponsor to justify amount and type of reserve samples	211.122.
4.1.2.2	System for prompt retrieval of PHS specimens and linkage to medical records (recipient and source animal).	312.57(a).
4.1.2.3	Notify FDA of a clinical episode potentially representing a xenogeneic infection.	312.32.
4.2.2.1	Document collaborations (transfer of obligation)	312.52.
4.2.3.1	Develop educational materials (sponsor provides investigators with information needed to conduct investigation properly).	312.50.
4.3	Sponsor to keep records of receipt, shipment, and disposition of investigative drug; investigator to keep records of case histories.	312.57 and 312.62(b).

[1] The "Public Health Service Policy on Humane Care and Use of Laboratory Animals" (*https://olaw.nih.gov/policies-laws/phs-policy.htm*).
[2] AAALAC International Rules of Accreditation (*https://www.aaalac.org/accreditation-program/rules-of-accreditation/*).
[3] The NRC's "Guide for the Care and Use of Laboratory Animals."

Based on a review of the information collection since our last request for OMB approval, we have adjusted our burden estimate which has resulted in a burden increase of 3.09 hours (new total of 62.12 hours) from our previous estimate of 59.03 hours. Change in the increase in burden was the result of the change of the number of recordkeepers due to the change in the number submission of IND's sponsors and a change in the number of animal source facilities.

Dated: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–07568 Filed 4–30–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4467]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by June 2, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910–0297. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, 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.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug User Fee Program

OMB Control Number 0910–0297—Revision

This information collection supports implementation of the FDA Prescription Drug User Fee program (called ''PDUFA'' in reference to the Prescription Drug User Fee Act). Under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 735 and 736 (21 U.S.C. 379g and 379h)), we have the authority to assess and collect annual program fees for prescription drug products approved under certain new drug applications (NDAs) and biologics license applications (BLAs). Also under this authority, pharmaceutical companies pay an application fee for certain NDAs and BLAs submitted to FDA for review. Because the submission of user fees concurrently with applications is required, review of an application by FDA cannot begin until the fee is submitted.

PDUFA must be reauthorized every 5 years. The FDA User Fee Reauthorization Act of 2022 (PDUFA VII) included the reauthorization of PDUFA through September 30, 2027 (*https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027*). PDUFA VII provides for the continued timely review of NDAs and BLAs. Since the initial passage of PDUFA, user fees have played an important role in expediting the drug review and approval process. PDUFA VII reauthorization also includes commitments to meet certain performance goals and procedures. The commitment goals represent the product of FDA's discussions with the regulated industry and public stakeholders, as mandated by Congress.

We are revising the collection to include our current commitment goals, as set forth in the document ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027,'' found on our website at *https://www.fda.gov/media/151712/download?attachment.* The commitment goals represent the product of FDA's discussions with the regulated industry and public stakeholders, as mandated by Congress. FDA is committed to meeting these goals and to continuous operational improvements associated with PDUFA implementation. The commitment goals provide for the development and issuance of topic-specific guidance. We maintain a searchable guidance database on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* In publishing the respective notices of availability for each guidance document, we include an analysis under the PRA and invite public comment on the associated information collection recommendations. In addition, all Agency guidance documents are issued in accordance with our Good Guidance Practices regulations in 21 CFR 10.115, which provide for public comment at any time.

To assist respondents with the information collection, we developed Form FDA 3397 entitled ''Prescription Drug User Fee Cover Sheet.'' Additional information and associated instructions may be found on our website at *https://www.fda.gov/industry/fda-user-fee-programs.* The cover sheet (Form FDA 3397) is submitted for original NDAs, BLAs, and resubmissions of these original applications after withdrawal before filing or refusal to file actions. The form is not submitted for certain FDA-regulated products. The list of exempted products is included under the instructions to Form FDA 3397.

Relatedly, sections 735 and 736 of the FD&C Act also provide for waiver, reduction, exemption, and refund requests. We developed the guidance document entitled ''Guidance for Industry—Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products,'' and Form FDA 3971 (Small Business Waiver and Refund Request), which can be found on our website at *https://www.fda.gov/media/131797/download.*

To assist respondents in understanding user fees associated with the information collection, we have developed the guidance document entitled ''Assessing User Fees Under the Prescription Drug User Fee Amendments of 2022'' (July 2023). The guidance explains the various fee assessments, procedures for payments and refunds, as well as other topics, and is available on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-user-fees-under-prescription-drug-user-fee-amendments-2022.*

The PDUFA information collection and all user fee cover sheets, including the ''Prescription Drug User Fee Cover Sheet'' (Form FDA 3397), are accessed and submitted electronically, as required by statute, through FDA's electronic systems such as the Document Archiving Reporting and Regulatory Tracking System (DARRTS), Electronic Submission Gateway (ESG), and Panorama.

In the **Federal Register** of November 18, 2024 (89 FR 90705), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment on the information collection indicating general support for the program. The commenter requested better reporting of additional information that is not currently collected for the PDUFA program and additional reports of new drug and biologic application review metrics, improved electronic submissions, and automated data exchange. We will consider the comment in future PDUFA negotiations.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Prescription drug user fee activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Sections 735 and 736 of the FD&C Act (PDUFA waivers and exemptions, not including small business waiver requests).	99	1.828	181	17	3,077
Section 736(d)(1)(C) of the FD&C Act and Form FDA 3971 (small business waivers).	35	1	35	2	70
Reconsideration Requests	13	1.69	22	24	528
Appeal Requests	4	1.5	6	12	72

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Prescription drug user fee activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
User Fee Cover Sheet Form FDA 3397 submission with original NDAs and BLAs.	132	1.24	164	0.5 (30 minutes)	82
Total	.....	.....	408	.....	3,829

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

Based on a review of Agency records, we estimate that the number of initial waiver requests submitted annually (excluding small business waiver requests under section 736(d)(1)(C) of the FD&C Act) is 181, submitted by 99 different applicants.

We estimate that 35 respondents will each submit a small business waiver request annually. We have included in the burden estimate the time for preparation and submission of application fee waivers for small businesses, including completion of Form FDA 3971. Small businesses requesting a waiver must submit documentation to FDA, including the number of their employees, as well as information that their application is their first human drug application, within the meaning of the FD&C Act, to be submitted to the Agency for approval.

We estimate receiving 22 requests for reconsideration annually (including small business waiver reconsiderations) and assume the average burden for preparing and submitting each request is 24 hours. In addition, we estimate receiving six requests annually for appeal of user fee waiver determinations, and assume the time needed to prepare an appeal is 12 hours. We have included in this estimate both the time needed to prepare the request for appeal to the Chief Scientist and User Fee Appeals Officer within the Office of the Commissioner, and the time needed to create and send a copy of the request for an appeal to the Director Division of User Fee Management within the Office of Management at FDA's Center for Drug Evaluation and Research.

We assume a total of 82 hours of burden for completing and submitting the 164 forms FDA 3397 (Prescription Drug User Fee Coversheet) along with submission of NDAs or BLAs. The burdens associated with submission of NDAs and BLAs are included in OMB control numbers 0910–0001 and 0910–0338, respectively.

The information collection reflects changes and adjustments. We have clarified that the scope of the collection includes provisions found in our current commitment goals letter, negotiated with industry, pertaining to the assessment of fees, waivers, refunds, and exemptions under PDUFA VII. We have also included relevant Agency guidance documents that provide instruction in this regard and for which we attribute attendant burden. Cumulatively, these adjustments have resulted in a total decrease of 3 responses and an overall increase of 203 burden hours annually since the prior renewal of the information collection. We attribute the minor changes in the numbers to normal fluctuations in numbers of waivers, exemptions, reconsideration requests, and appeals received for assessed PDUFA fees. We do not attribute a change in the burden related to the revision request to include the Agency's commitment goals.

Dated: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–07574 Filed 4–30–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3675]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Pharmaceutical Distribution Supply Chain; Drug Supply Chain Security

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by June 2, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0806. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, 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.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Pharmaceutical Distribution Supply Chain; Drug Supply Chain Security

OMB Control Number 0910–0806—Revision

This information collection helps support implementation of sections 581 and 582 (21 U.S.C. 360eee and U.S.C. 360eee–1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which govern the pharmaceutical distribution supply chain. Definitions set forth in section 581 of the FD&C Act prescribe specific activities that apply to the individuals identified in section 582, including recordkeeping requirements intended to effectuate the tracing of certain pharmaceutical drugs as they are distributed within the United States. The recordkeeping provisions expressly provided for in sections 582(b) through (e) of the FD&C Act cover tasks associated with product identification, product tracing, transaction data, record verification, and disclosures (exchange)