

United States Food and Drug Administration

Prescription Drug User Fee Program

OMB Control No. 0910-0297 - Revision

SUPPORTING STATEMENT

**Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of the Food and Drug Administration (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 (the 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 five years. The FDA User Fee Reauthorization Act of 2022 (PDUFA VII) includes 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 new drug and biologic license applications. 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 commitment 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 <http://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027>. 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, including guidance pertaining to the assessment and submission of user fees. 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 new drug applications, biological license applications 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*,” (October 2019) 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: <http://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-user-fees-under-prescription-drug-user-fee-amendments-2022>.

We are requesting OMB approval of the information collection associated with our PDUFA program, including Forms FDA 3397, FDA 3971, and the associated guidance documents, as discussed in this supporting statement.

## 2. Purpose and Use of the Information Collection

The purpose of the information collection is to facilitate FDA assessments regarding whether a fee is required for the review of an application; determining the amount of required program fees; accounting for and tracking fees, and, as necessary, providing for waivers, reductions, and refunds. FDA forms provide a means to cross-reference applications and fee submissions utilizing a unique number tracking system. It also identifies pertinent statutory provisions under which the application may qualify for a fee exemption.

## 3. Use of the Improved Information Technology and Burden Reduction

The information collection is administered electronically, as required by statute, through FDA’s electronic systems such as Document Archiving Reporting and Regulatory Tracking System (DARRTS), Electronic Submission Gateway (ESG), and Panorama. We continue to evaluate ways to improve our systems interface capabilities and employ enhancements as limited agency resources permit. All user fee cover sheets, including the *Prescription Drug User Fee Cover Sheet* Form FDA 3397 and *Small Business Waiver and Refund Request Form*

FDA 3971, are accessed and submitted electronically. We continue to improve technology and pursue methods of reporting that will facilitate submissions.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. We maintain other information collections pertaining to other user fee programs intended to cover the respective FDA-regulated products for which the fees are authorized.

5. Impact on Small Businesses or Other Small Entities

The information collection imposes no undue burden on small entities, but rather, provides for waivers and exemptions. User fees are assessed in accordance with statutory requirements and waivers are granted for respondents who qualify as a small business. Finally, CBER's Office of Communication, Outreach, and Development, Division of Manufacturers Assistance and Training, and CDER's Office of Communication, Division of Drug Information provides assistance to small businesses subject to FDA's regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements, as well as those timeframes set forth in current agency and industry commitment goals.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60 day notice for public comment in the Federal Register of November 18, 2024 (89 FR 90705). 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. No other comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Data will be kept private to the extent allowed by law.

### The Privacy Act of 1974

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3397 (Prescription Drug User Fee Coversheet) and Form FDA 3971 (Small Business Waiver and Refund Request) is business contact name, business phone number, business email address, business mailing address, and business fax number. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

### The Freedom of Information Act

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

#### 11. Justification for Sensitive Questions

The information does not include questions of a sensitive nature.

#### 12. Estimates of Annualized Burden Hours and Costs

##### 12a. *Estimated Annual Hourly Burden*

Table 1.--Estimated Annual Reporting Burden

Prescription Drug User Fee Activity	No. of Respondents	No. 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 waivers)	99	1.82	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

Prescription Drug User Fee Activity	No. of Respondents	No. 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 mins.)	82
Total			408		3,829

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 determination, 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 the new drug applications or biologics license applications. The burdens associated with submission of new drug applications and biologics license applications are included in OMB control numbers 0910-0001 and 0910-0338, respectively.

#### *12b. Annualized Cost Burden Estimate*

Table 2. – Estimated Cost to Respondents

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Reporting	82	\$74.46 <sup>1</sup>	\$6,105.72

<sup>1</sup>NAICS Occupation code 11-3000 (Operations Specialties Managers  
[www.bls.gov/oes/current/naics4\\_325400.htm](http://www.bls.gov/oes/current/naics4_325400.htm))

The cost to respondents assumes the wage rate of a regulatory affairs specialist, \$74.46 per hour, responsible for completing and submitting the Prescription Drug User Fee Cover Sheet. This salary estimate includes benefits, but no overhead costs.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Costs of administering the information collection are absorbed from collected user fees. The Center for Drug Evaluation and Research and the Center for Biologic Evaluation and Research dedicate approximately fourteen (14) FTEs total at the fully loaded cost of \$336,269/FTE ( $14 \times \$336,269 = \$4,707,766$  annually) to the administration of the PDUFA program.

15. Explanation for Program Changes or Adjustments

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 commitment goals.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB control number as required by 5 CFR 1320.5 (and 21 CFR 1320.8(b)(1)); however, because documents are more frequently being accessed electronically we are implementing technological changes that enable us to display the expiration date by linking to approval information found at [www.reginfo.gov](http://www.reginfo.gov). We intend to include the OMB control number and expiration date on the guidance landing page, allowing those who download the document an easily identifiable option to view this information. This also allows the agency to more easily update the expiration date upon renewal and/or revision of OMB approval. We are taking this approach to improve compatibility with our current website platform.

Display of the OMB expiration date as required by 5 CFR 1320.5 is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.