

UNITED STATES FOOD & 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, the agency, us or we) 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 user fees for certain new drug applications (NDAs) and new biologics license applications (BLAs). Also under this authority, pharmaceutical companies pay a 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.

We are revising the information collection to include reference to our current commitment goals, as set forth in the document “*PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022*,” also found on our website at <https://www.fda.gov/media/99140/download>, and also included as a relevant authority in OMB control no. 0910-0001 (*Applications for FDA Approval to Market a New Drug*). PDUFA is currently authorized through September 30, 2022, with reauthorization activities currently underway. 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, 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>.

To assist respondents with the information collection, we developed Form FDA 3397 entitled “*PDUFA 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) need not be submitted for certain FDA-regulated products, e.g., generic drugs, and whole blood and blood components for transfusion. 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, refund, and reconsideration 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>. We are also revising the information collection to include provisions associated with section 736(a)(1)(F) of the FD&C Act pertaining to an orphan drug designated product – those products that are the subject of an NDA that are intended to treat a rare disease or condition. We have developed draft Form FDA 4068, “*Prescription Drug User Fee Act; Waivers, Refunds, and Exemptions*,” along with accompanying instructions, to enable sponsors of designated orphan products to request an exemption from applicable fees under PDUFA. We are currently soliciting public comment on the draft form, however we intend on finalizing the instrument to help encourage the development of these products.

We are therefore requesting OMB approval of the information collection associated with our PDUFA program, including Forms FDA 3397, FDA 3971, draft Form FDA 4068, 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 with regard to whether a fee is required for the review of an application; determining the amount of required 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 Submission Gateway (ESG). 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, are accessed and submitted electronically. We are not aware of any other improved technology, nor legal obstacles to reduce the burden, although we continue to 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 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. 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 2017*.” 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/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM580099.pdf> 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 provide 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 30, 2021 (87 FR 67958). No 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

The confidentiality of information submitted to FDA is consistent with the Freedom of Information Act (FOIA) and FDA's published regulations regarding "*Public Information*" (21 CFR Part 20). Proprietary or trade secret information is deleted from any information released by under the Freedom of Information Act.

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 <sup>1</sup>

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 – draft Form FDA 4068)	112	1.68	189	17	3,213
Section 736(d)(1)(C) of the FD&C Act and Form FDA 3971 (small business waivers)	37	1	37	2	74
Reconsideration Requests	6	1.67	10	24	240
Appeal Requests	1	1	1	12	12
User Fee Cover Sheet Form FDA 3397	174	1	174	0.5 (30 mins.)	87
Total			411		3626

<sup>1</sup> 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) will be 189, submitted by 112 different applicants; and that 37 respondents annually will each submit a small business waiver request. 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 the application is the first human drug application, within the meaning of the FD&C Act, to be submitted to the Agency for approval.

We estimate receiving 10 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 1 request 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 87 hours of burden for completing and submitting Form FDA 3397 (Prescription Drug User Fee Coversheet) for submission of a new drug application or biologics license application.

*12b. Annualized Cost Burden Estimate*

Table 2. – Estimated Cost to Respondents

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Reporting	87	\$72	\$6,264

The cost to respondents assumes the wage rate of a regulatory affairs specialist, \$72 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.

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. We have also added relevant agency guidance documents that provide instruction in this regard and for which we attribute attendant burden. Cumulatively these changes and adjustments result in a decrease of 34 responses and an increase in 865 hours annually.

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 considering technological changes that will 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 (Drupal).

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.