UNITED STATES FOOD & DRUG ADMINISTRATION

Prescription Drug User Fee Cover Sheet
Form FDA 3397

OMB Control No. 0910-0297

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, us or we) Prescription Drug User Fee program. 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)), as amended, we have the authority to assess and collect user fees for certain new drug applications (NDAs) and new biologics license applications (BLAs). Under this authority, pharmaceutical companies pay a fee for certain new 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.

To assist respondents in this regard, we developed Form FDA 3397 entitled, "*Prescription Drug User Fee Cover Sheet*." Instructions are found on our internet site at https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119184.htm. 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 on this form. We have also established a PDUFA page on our internet site - https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ that includes resources to assist respondents with questions regarding PDUFA topics.

We therefore request OMB approval of the information collection provisions included in Form FDA 3397 and associated instructions as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The purpose of the information collection is to collect the minimum necessary information to determine whether a fee is required for the review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application utilizing a unique number tracking system. It also identifies pertinent statutory provisions under which the application may qualify for a fee exemption. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and FDA's Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of NDAs and BLAs.

3. Use of the Improved Information Technology and Burden Reduction

The Prescription Drug User Fee Cover Sheet, Form FDA 3397, is 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

Although we administer a number of user fee programs, this information collection specifically supports user fees associated with certain new drug applications (NDAs) and new biologics license applications (BLAs).

5. Impact on Small Businesses or Other Small Entities

The information collection imposes no undue burden on small entities. 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 Prescription Drug User Fee Cover Sheet is not used for the periodic collection of information. Rather, the form is to be used once for each specific application at the time of submission. Its intent is to provide specific information to allow us to determine that the correct fee, if any, has been paid to allow prompt acceptance and initiation of the review of NDAs and BLAs. There can be no less frequent information collection than one request per application without the consequence of potential delay of acceptance of applications for which information necessary to process them is not provided.

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 August 24, 2018 (83 FR 42900). 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

There are no questions of a sensitive nature applicable to the information collection.

12. Estimates of Annualized Burden Hours and Costs

The total estimated annual burden for this collection of information is 131 hours as reflected below.

12a. Annualized Hour Burden Estimate

Table 1. – Estimated Annual Reporting Burden

FDA Form No.	No. of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3397	155	1.6903	262	0.50 (30 minutes)	131

Respondents to this collection of information are new drug and biologics manufacturers. Based on our database system for fiscal year FY 2017, there are an estimated 155 manufacturers of products subject to the Prescription Drug User Fee Act (Pub. L. 105-115). The total number of annual responses is based on the number of submissions we received in FY 2017. CDER received 250 annual responses that include 218 NDAs and 32 BLAs: CBER received 12 BLAs. The estimated hours per response are based on past our experience with the various submissions.

12b. Annualized Cost Burden Estimate

Table 2. – Estimated Cost to Respondents

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Reporting	131	$72	$9,432

The cost to respondents is based on the salary of a regulatory affairs specialist, at a pay rate of $72 per hour, who is responsible for filling out 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

The estimated annual cost to FDA is $14,934.

Table 3. – Estimated Cost to Federal Government

Activity	Number of Responses	Hours per Response	Cost per Hour	Total Cost
Form FDA 3397	262	1.0	$57	$14,934

The estimated cost assumes User Fee staff at an average grade of GS12-5. The estimate of one hour includes the time associated with the support, review, data entry, and tracking related to the Prescription Drug User Fee Cover Sheet. The salary includes benefits but no overhead costs.

15. Explanation for Program Changes or Adjustments

The information collection reflects adjustments. We have decreased the burden estimate by 1,724 hours and 3,447 responses to reflect a decrease in submissions. We attribute the reduction to the restructuring of the Prescription Drug Use Fee Program fees. The FD&C Act, as amended by the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), authorizes FDA to collect application fees for certain applications for the review of human drug and biological products and discontinued the supplement fee. This resulted in the removal of supplements from the Prescription Drug User Fee Cover Sheet, therefore reducing the burden for this collection of information.

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

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.