Prescription Drug User Fee Cover Sheet - Form FDA 3397

OMB # 0910-0297

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting an extension of Office of Management and Budget (OMB) Control No. 0910-0297 and OMB approval for the collection of information for the Form FDA 3397, Prescription Drug User Fee Cover Sheet (Tab A).

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, FDA has the authority to assess and collect user fees for certain new drug applications (NDAs) and new biologics license applications (BLAs) and supplements to those applications. Under this authority, pharmaceutical companies pay a fee for certain new NDAs, BLAs, or supplements to NDAs or BLAs submitted to the Agency for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application or supplement by FDA cannot begin until the fee is submitted. The Prescription Drug User Fee 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.

2. Purpose and Use of the Information Collection

The Prescription Drug User Fee Cover Sheet, Form FDA 3397, is required to be included with each applicable NDA, BLA, and supplemental application to an NDA or BLA submitted to FDA for review. The Prescription Drug User Fee Cover Sheet is designed to provide the minimum necessary information to determine whether a fee is required for the review of an application or supplement, 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 or supplement 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 Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of NDAs, BLAs, and/or supplemental applications to NDAs or 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.

FDA is not aware of any other improved technology to reduce the burden. FDA continues to pursue methods of applying technology to further reduce the burden to the respondents of the collection of information.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency that requires this information. The required information is not available from any other source.

5. Impact on Small Businesses or Other Small Entities

This collection of information applies to small as well as large facilities. Although FDA must apply the statutory and regulatory requirements to all enterprises, FDA does provide special help to small businesses. 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.

The prescription drug user fee provisions of the FD&C Act include a waiver provision for small businesses. Businesses that have been granted a waiver of fees under this provision can note their waiver from the fee requirement by utilizing the Prescription Drug User Fee Cover Sheet.

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 or supplement at the time of submission. Its intent is to provide specific information to allow FDA to determine that the correct fee, if any, has been paid to allow prompt acceptance and initiation of the review of NDAs, BLAs, and supplements to these applications. 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), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of April 15, 2015 (80 FR 20232). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift was provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

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

11. Justification for Sensitive Questions

Questions of a sensitive nature are not applicable to this collection of information.

12. Estimates of Annualized Burden Hours and Costs

The total estimated annual burden for this collection of information is 1,855 hours.

12 a. Annualized Hour Burden Estimate

FDA Form No.	No. of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3397	290	12.79	3,710	0.50 (30 minutes)	1,855

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's database system for fiscal year (FY) 2014, there are an estimated 290 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 received by FDA in FY 2014. CDER received 3,005 annual responses that include the following submissions: 128 NDAs; 7 BLAs; 1,586 manufacturing supplements; 1,081 labeling supplements; and 203 efficacy supplements. CBER received 705 annual responses that include the following submissions: 11 BLAs; 611

manufacturing supplements; 64 labeling supplements; and 19 efficacy supplements. The estimated hours per response are based on past FDA experience with the various submissions.

12 b. Annualized Cost Burden Estimate.

Cost to Respondents

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Reporting	1,855	$56	$103,880

The cost to respondents is based on the salary of a regulatory affairs specialist, at a pay rate of $56 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, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The estimated annual cost to FDA is $200,340.

Activity	Number of Responses	Hours per Response	Cost per Hour	Total Cost
Form FDA 3397	3,710	1.0	$54	$200,340

The estimated cost is based on FDA office and 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 previous burden estimate was 2,065.5 hours. The current decrease in burden to 1,855 hours (-210.5 hours) is mostly attributed to the decrease in the number of certain supplements (mostly manufacturing supplements submitted to CDER) submitted to FDA under total annual responses. The overall decrease is due to the normal variation in the submission of applications and supplements to FDA.

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 is not seeking approval to exempt display of the expiration date of the OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.