User Fee Cover Sheet - Form FDA 3397

OMB # 0910-0297

SUPPORTING STATEMENT

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, User Fee Cover Sheet (Tab A).

Under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h), the Prescription Drug User Fee Act of 1992 (PDUFA) (Public Law 102-571), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115), the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which includes the Prescription Drug User Fee Amendments of 2002 (Public Law 107-188), and most recently by the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85), FDA has the authority to assess and collect user fees for certain drug and biologics license applications and supplements. Under this authority, pharmaceutical companies pay a fee for certain new human drug applications, biologics license applications, or supplements submitted to FDA 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. Form FDA 3397 need not be submitted for generic drugs, blood for transfusion, in vitro diagnostic biological products licensed under Section 351 of the PHS Act (42 USC 262), and certain other FDA-regulated products.

2. Purpose and Use of the Information Collection

The User Fee Cover Sheet, Form FDA 3397, is designed to be included with each new drug application, biologics license application, and supplemental application submitted to FDA for review. The 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, to determine the amount of the fee required, and to account for and track user fees. It provides a cross-reference of the fee submitted for an application with the actual 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 Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new drug applications, biologics license applications and/or supplemental applications.

3. Use of the Improved Information Technology and Burden Reduction

The User Fee Cover Sheet can be accessed and submitted electronically. FDA is not aware of any other improved technology to reduce the burden.

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

FDA believes that its duty requires equal application of the regulations to all enterprises. While FDA does not believe it can apply different standards with respect to statutory requirements, FDA does provide special help to small businesses. CBER's Office of Communication, Outreach, and Development, Division of Manufacturers Assistance and Training provides assistance to small businesses subject to regulatory requirements. CDER's Office of Communication, Division of Drug Information also provides assistance to small businesses.

PDUFA includes 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 this User Fee Cover Sheet.

6. Consequences of Collecting the Information Less Frequently

The 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 new drug applications, biologics license applications and supplements. 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 the collection of information requirements.

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 June 8, 2009 (74 FR 27145). We received one public comment regarding the collection of information. The comment was outside the scope of the Paperwork Reduction Act and did not provide any data or explanation that would support a change regarding the information collection requirements.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift was provided or will be 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 the agency's published regulations of "Public Information" under 21 CFR Part 20.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

The total estimated annual burden for this collection of information is 1,959 hours.

Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3397	255	15.36	3,917	0.50	1,959

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's database system for fiscal year (FY) 2008, there are an estimated 255 manufacturers of products subject to the user fee provisions of PDUFA. The total number of annual responses is based on the number of submissions received by FDA in FY 2008. CDER received 3,107 annual responses that include the following submissions: 147 new drug applications; 13 biologics license applications; 1,813 manufacturing supplements; 987 labeling supplements; and 147 efficacy supplements. CBER received 810 annual responses that include the following submissions: 9 biologics license applications; 743 manufacturing supplements; 48 labeling

supplements; and 10 efficacy supplements. Based on previous submissions that were received, the rate of these submissions is not expected to change significantly in the next few years. The estimated hours per response are based on past FDA experience with the various submissions, and the average is 30 minutes.

Cost to Respondents

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	1,959	$48	$94,032

The cost to respondents is based on the salary of a regulatory affairs specialist, at a pay rate of $48 per hour, who is responsible for filling out and submitting the User Fee Cover Sheet. This salary estimate includes benefits but no overhead costs.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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

14. Annualized Cost to the Federal Government

The estimated annual cost to FDA is $180,182.

Activity	Number of Responses	Hours per Response	Cost per Hour	Total Cost
Form FDA 3397	3,917	1.0	$46.00	$180,182

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 User Fee Cover Sheet. The salary includes benefits but no overhead costs.

15. Explanation for Program Change or Adjustments

The estimated total annual burden for this information collection requirement was 1,128 hours in 2006. The current increase in burden to 1,959 hours (+831 hours) is mostly attributed to the increase in the hours per response from 0.3 hours to 0.5 hours. The hours per response were revised for consistency with the OMB statement on the form. The total annual responses slightly increased from 3,761 in FY 2005 to 3,917 in FY 2008.

FDA is revising Form FDA 3397 by: (1) Including an additional question regarding redemption of a priority review voucher; (2) deleting the exclusion for certain applications submitted under

section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act; and (3) making several minor editorial changes. The hours per response is not effected by these changes.

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 Appropriate

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

N/A