

SUPPORTING STATEMENT for
User Fee Cover Sheet - Form FDA 3397
OMB # 0910-0297

JUSTIFICATION

1. Need and Legal Basis

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), and 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) (Tab B), 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 to these applications submitted to FDA for review. Generic drugs, blood for transfusion, medical devices, in vitro diagnostic products, and other FDA-regulated products are not covered by this legislation.

2. Information Users

The User Fee Cover Sheet is designed to be included with each new drug application, biologics license application, and supplemental application submitted to FDA for review. The information collected will be used by the FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of an application or supplement. The form 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 reduced fee or be excluded from the requirement for a fee.

PDUFA, as amended by FDAMA and the Prescription Drug User Fee Amendments of 2002, requires the submission of the User Fees concurrently with applications. If the required fees are not submitted, the review of the application can not begin. The User Fee Cover Sheet provides the information necessary to either initiate or defer the application review.

3. Improved Information Technology

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

4. Duplication of Similar Information

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

5. Small Businesses

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, Training, and Manufacturer's Assistance provides assistance to small businesses subject to regulatory requirements. CDER's 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 exclusion from the fee requirement by utilizing this User Fee Cover Sheet.

6. Less Frequent Collection

This form 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 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

There are no special circumstances for the collection of information requirements.

8. Federal Register Notice/Outside Consultation

In accordance with 5 CFR 1320.8(d), on May 25, 2006 (71 FR 30144), a 60-day notice for public comment (Tab C) was published in the **Federal Register**. No comments were received from the public.

9. Payment/Gift Offered to Respondent

No payment or gift was provided or will be provided to respondents.

10. Confidentiality

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 which prohibit FDA from releasing to the public any information that cannot be disclosed. Such information is deleted from any information released by FDA under FOIA and FDA regulations.

11. Sensitive Questions

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

12. Burden Estimate (Total Hours and Wages)

The total estimated annual burden for this collection of information is 1,128 hours.

Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3397	243	15.48	3,761	0.30	1,128

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's database system for fiscal year (FY) 2005, there are an estimated 243 manufacturers of products subject to PDUFA. However, not all manufacturers will have any submissions and some may have multiple submissions in a given year. The total number of annual responses is based on the number of submissions received by FDA in FY 2005. CDER estimates 3,085 annual responses that include the following: 101 new drug applications; 3 biologics license applications; 1,915 chemistry supplements; 921 labeling supplements; and 145 efficacy supplements. CBER estimates 676 annual responses that include the following: 6 biologics license applications; 614 manufacturing supplements; 46 labeling supplements; and 10 efficacy supplements. Based on previous estimates, the rate of 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 range from 5 to 30 minutes. The hours per response are based on the average of these estimates.

Cost to Respondents

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	1,128	\$42	\$47,376

The cost to respondents is based on the salary of a regulatory affairs specialist, at a pay rate of \$42 per hour, who is responsible for filling out and submitting the application. This salary estimate includes benefits but no overhead costs.

13. Capital Costs (Maintenance of Capital Costs)

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

14. Cost to Federal Government

The estimated annual cost to FDA is \$62,057.

Activity	Number of Responses	Hours per Response	Cost per Hour	Total Cost
Form FDA3397	3,761	0.75	\$22	\$62,057

The estimated time for review, data entry, and tracking is 45 minutes. The information from the form will be extracted by both program and administrative support personnel (GS-4 through GS-7) with an average salary (including benefits but no overhead costs) of \$22 an hour.

15. Program or Burden Changes

The estimated total annual burden for this information collection requirement was 969 hours in 2003. The current increase to 1,128 burden hours is mostly attributed to the increased number of respondents and total annual responses received.

16. Publication and Tabulation Dates

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

17. Display of OMB Approval Date

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

18. Exceptions to “Certification for Paperwork Reduction Act Submissions”

There are no exceptions to Item 19 of OMB Form 83-I.