

OMB INFORMATION COLLECTION  
SUPPORTING STATEMENT  
0910-0297

User Fee Cover Sheet - Form FDA 3397

**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 (Public Law 105-115, Tab B), FDA has the authority to assess and collect user fees for certain drug and biologics marketing applications and their 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 the agency 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. Purpose and Use of the Information**

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 requires the submission of the User Fees concurrently with applications. If the required fees are not submitted, the review of the application will not begin. The User Fee Cover Sheet provides the information necessary to either initiate or defer the application review.

**3. Use of Information Technology and Burden Reduction**

The User Fee Cover Sheet form is designed to provide the minimum needed information to determine whether a fee is required for the review of an application, to determine the amount of

fee required, and to account for and track User Fees. 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 the 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 also has a contact for small businesses located in the Drug Information Branch.

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 Use Fee Cover Sheet.

#### **6. Consequences of Collecting the Information Less Frequently**

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, biologic product 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 Agency**

In accordance with 5 CFR 1320.8(d), a 60-day notice for public comment on the information collection provisions was published in the **Federal Register** of August 18, 2000 (65 FR 50541, Tab C). *No comments were received from the public.*

**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 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. Justification for Sensitive Questions**

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

**12. Estimates of Hour Burden Including Annualized Hourly Costs**

The estimated annual burden for this information collection is 876 hours.

Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3397	208	14.4	2,921	0.30	876

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's data base system, there are an estimated 208 manufacturers of products subject to PDUFA. However, not all manufacturers will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the number of submissions received by FDA in fiscal year 1999. CDER estimates 2,478 annual responses that include the following: 125 new drug applications, 1,458 chemistry supplements, 755 labeling supplements, and 140 efficacy supplements. CBER estimates 443 annual responses that include the following: 8 biologics license applications, 396 manufacturing (chemistry) supplements, 29 labeling supplements and 10 efficacy supplements. 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	876	\$35	\$30,660

The cost to respondents is based on the salary of a regulatory affairs specialist, at a pay rate of \$35 per hour, who is responsible for filling out, signing, and submitting the application. This salary estimate includes benefits but no overhead costs.

**13. Estimate of Other Total Annual Cost Burden to Respondents or Record-keepers**

There are no capital and start-up, or operation, maintenance and purchase costs associated with this information collection.

**14. Annualized Costs to the Federal Government**

The estimated annualized cost to the Federal Government is \$39,434.

Activity	Number of Responses	Hours per Response	Cost per Hour	Total Cost
Form FDA3397	2,921	0.75	\$18	\$39,434

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 not overhead) of \$18 an hour.

**15. Explanation of Program Changes or Adjustments**

The estimated total annual burden for this information collection requirement was 283 hours in 1997. The current increase to 876 burden hours is mostly attributed to the number of responses received and the estimated increase in the hours per response.

**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 for OMB approval.

**18. Exception to Certification for Paperwork Reduction Act Submissions**

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