Generic Drug User Fee Cover Sheet – Form FDA 3794
0910-NEW
SUPPORTING STATEMENT

Justification

1. Circumstances Making the Collection of Information Necessary

On July 9, 2012, the Generic Drug User Fee Amendments (GDUFA) (Pub. L. 112-144, Title 111) was signed into law by the President. GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to the industry. Section 744B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.), as added by GDUFA, authorizes the Food and Drug Administration (FDA), beginning fiscal year 2013, to assess and collect the following fees related to generic drugs: (1) a one-time backlog fee for abbreviated new drug applications (ANDAs) pending on October 1, 2012; (2) a drug master file (DMF) fee for Type II active pharmaceutical ingredient (API) DMFs referenced on or after October 1, 2012, in a generic drug submission and for which the DMF fee has not already been paid; (3) a filing fee for ANDAs, a prior approval supplements (PAS), or applicable amendments to an ANDA or a PAS, as well as an additional fee for API information not included by reference to a Type II API DMF; and (4) an annual facility fee for a generic drug facility which is identified or intended to be identified in at least one generic drug submission that is pending or approved to produce a finished dosage form (FDF) of a human generic drug or an API contained in a human generic drug.

2. Purpose and Use of the Information Collection

Proposed Form FDA 3794, the Generic Drug User Fee Amendments Cover Sheet, requests the minimum necessary information from applicants to

determine the total amount of generic drug user fees required, and to account for and track user fees. Generic drug application holders and API and/or FDF facility's owner will fill out the cover sheet to accompany payment. While the applicants and manufacturers may choose among several methods of payments, all applicants must create and/or submit all GDUFA Cover Sheets by using the FDA's web-based electronic User Fee System.

Upon submission of a completed cover sheet, the User Fee System automatically generates a user fee payment identification number. FDA requests that applicants provide a copy of this completed cover sheet along with an ANDA, an applicable supplement, or a type II API DMF so that the FDA can verify that the applicant has satisfied all relevant user fee obligations.

The information collected would be used by the FDA's Center for Drug Evaluation and Research (CDER) to initiate the administrative screening of a generic drug submission and the completeness assessment of a type II API DMF, and to track all generic drug user fees.

3. Use of Improved Information Technology and Burden Reduction

Applicant will create and/or submit a Generic Drug User Fee Cover Sheet electronically by accessing the User Fee System. Important information such as the applicant's name and address, as well as the name, telephone number, and email address of the applicant's representative and/or United States agent, would be auto-populated if the organization has registered and has an existing user fee account in the User Fee System. In addition, the FDA has partnered with Dun & Bradstreet (D&B) to allow new users to locate their organizations in the D&B

database. If an organization is found in the D&B database, it will be auto-populated as the new user completes the registration process.

4. Efforts to Identify Duplication and Use of Similar Information

The information collection is not available from any other source. FDA's review of a generic drug submission and financial systems are currently not integrated. Therefore, some duplication of effort is inherent in this collection. FDA is exploring methods to integrate the IT systems such that it could address this two-step approach. However, FDA must weigh the costs of system integration with the high volume and complexity of the GDUFA program.

5. Impact on Small Businesses or Other Small Entities

This information collection applies to all human generic drug companies. Since the majority of them are small companies, the requested information has been held to the absolute minimum required for the intended use of collected data to carry out the GDUFA program.

6. Consequences of Collecting the Information Less Frequently

Potential or actual human generic drug application holders are required to complete the proposed form for each ANDA, PAS, an applicable amendment to an ANDA or a PAS, backlog ANDA, or type II API DMF referenced for the first time on or after October 1, 2012. In addition, a generic drug facility which is identified or intended to be identified in at least one generic drug submission that is pending or approved to produce an FDF of a human generic drug or an API contained in a human generic drug is required to complete the proposed form annually. A collection of information that is less frequent than that proposed will

result in delays in reviewing of generic drug applications and supplements, and completeness assessment of type II API DMFs.

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 July 26, 2012 (77 FR 43844). FDA received the following comment:

Comment: Small generic manufacturers will heavily suffer from the establishment fees under GDUFA.

Response: FDA notes this comment is outside the scope of the proposed collection of information, Form FDA 3794 (Generic Drug User Fee Cover Sheet)

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 would be handled consistent with the Freedom of Information Act (FOIA) and FDA's published regulations under 21 CFR Part 20, which prohibit FDA from releasing to the public any information that cannot be disclosed.

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

12 a. Annualized Hour Burden Estimate

Respondents to this proposed collection of information would be potential or actual generic application holders and/or related manufacturers (manufacturers of FDF and/or APIs). Companies with multiple applications will submit the proposed form for each application and facility. Based on FDA's database of human generic drug application holders and related manufacturers and results of generic drug user fee negotiations between the Agency and representatives of regulated industry, FDA estimates that 500 companies would submit a total of 3,850 cover sheets annually to pay for application and facility user fees. FDA estimates that the 3,850 annual cover sheet responses would break down as follows: 2,000 for facility fees, 750 for ANDAs, 750 for PASs, and 350 for Type II API DMFs. FDA also estimates that the one-time backlog fee would affect 350 application owners sponsoring 2,700 applications. The estimated hours per response, based on FDA's past experience with similar submissions, will likely range from approximately 0.1 to 0.5 hours. The hours per response are estimated at the upper end of the range to be conservative.

The FDA estimates the burden of this collection of information as follows:

Table 1: Estimated annual reporting burden for all applicable applications and fees except the backlog fee

Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3794	500	7.7	3,850	0.5	1,925

The backlog fee is a one-time fee. FDA expects the majority of these fees to be received in the first year only. The estimated reporting burden for the backlog fee is shown in table 2 of this document.

Table 2: Estimated one-time annual reporting burden for backlog fee

Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3794	350	7.7	2,700	0.5	1,350

12b. Annualized Cost Burden Estimate

The estimated annual costs to respondents for all applicable applications and fees except backlog fee and for only the backlog fee are $88,550 and $62,100, respectively. The costs are based on a regulatory affairs specialist's pay rate at $46/hour. The estimated average hourly pay rate includes benefits but no overhead costs.

Table 3: Estimated annual reporting cost burden for all applicable applications and fees except the backlog fee

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	1,925	46	88,550

Table 4: Estimated one-time annual reporting cost burden for backlog fee

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	1,350	46	62,100

13. Estimates of Other Total Annual Costs to Respondents and/or Record keepers/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 costs to FDA are $88,550 for all applicable applications and fees except the backlog fee and $31,050 for backlog fee only. These costs are based on FDA office and user fee staff at an average grade of GS 12-5. The estimate of one hour includes time and activities associated with the support, reviewing, data entry, and tracking related to the proposed form. The estimated hourly pay rate includes benefits but not overhead costs.

Table 5: Estimated annual cost to the Federal Government for all applicable applications and fees except the backlog fee

Form	Total Annual Responses	Hours per Response	Cost per Hour	Total Cost
FDA 3794	3,850	0.5	46	88,550

Table 6: Estimated one-time annual cost for backlog fee

Form	Total Annual Responses	Hours per Response	Cost per Hour	Total Cost
FDA 3794	1,350	0.5	46	31,050

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information of 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. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.