

UNITED STATES FOOD & DRUG ADMINISTRATION

Generic Drug User Fee Program

OMB Control Number 0910-0727

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of FDA’s Generic Drug User Fee program. The Generic Drug User Fee Amendments (GDUFA) (Pub. L. 112-144, Title 111) were enacted to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA authorizes FDA to assess user fees to fund critical and measurable enhancements to the performance of FDA’s generic drugs program, bringing greater predictability and timeliness to the review of generic drug applications. GDUFA is currently authorized through September 30, 2022, with reauthorization activities currently underway. For more information regarding GDUFA and ongoing implementation, we invite you to visit our website at <https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments>. GDUFA is based on an agreement negotiated by FDA and representatives of the generic drug industry intended to address continuing regulatory challenges. GDUFA reflects input received during an open process that includes regular public meetings, posting of meeting minutes, and consideration of comments from a public docket.

We are revising the information collection to include the current GDUFA agreement, or “goals letter,” as reflected in the document “*GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022*,” available for download from our website at <https://www.fda.gov/media/101052/download>. The performance goals and program enhancements specified in the goals letter apply to aspects of the generic drug review program that are important for facilitating timely access to quality, affordable generic medicines. FDA is committed to meeting the performance goals specified in the goals letter and to continuous improvement of its performance. Included among the performance goals is the issuance of topic-specific guidance documents. We maintain a searchable guidance database on our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. In publishing the respective notices of availability for each guidance document, we include an analysis under the PRA and invite public comment on any associated information collection recommendations. In addition, all agency guidance documents are issued in accordance with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time.

We have developed Form FDA 3794, the *Generic Drug User Fee Cover Sheet*, available at <https://www.fda.gov/industry/fda-user-fee-programs> to provide a uniform format for the submission of information necessary to account for and track user fees, and to determine the amount of the fee required.

We are therefore requesting approval of the information collection provisions associated with our GDUFA program, including the GDUFA cover sheet Form FDA 3794, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Respondents to the collection of information are potential or actual generic drug application holders or related active pharmaceutical ingredient and finished dosage form manufacturers. Companies with multiple user fee obligations will submit a cover sheet for each user fee obligation. Applicants complete the cover sheets to accompany payments. While applicants may submit payment through multiple means, all cover sheets are prepared using our web-based electronic User Fee System. Upon submitting the completed cover sheet, the User Fee System generates a user fee identification number, which is provided to applicants at the bottom of the cover sheet. It also notes the correct FY user fee assessment that is due for the submission/program. We request that applicants submit a copy of this completed cover sheet along with the abbreviated new drug application, and other GDUFA fees, so we can verify that the applicant has paid the correct user fee.

3. Use of Improved Information Technology and Burden Reductions

The information collection is administered electronically, as required by statute, through FDA's Electronic Submission Gateway (ESG). All user fee cover sheets, including the *Generic Drug User Fee Cover Sheet*, are accessed and submitted electronically. We are not aware of any other improved technology, nor legal obstacles to reduce the burden. We continue to pursue methods of reporting that will facilitate submissions as limited agency resources permit. 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, are auto-populated if the organization has registered and has an existing user fee account in the User Fee System. In addition, we have enabled new users to locate their organizations in the Dun & Bradstreet (D&B) database. If an organization is found in the D&B database, certain fields are auto-populated as the new user completes the registration process. We are unaware of any other improved technology that would facilitate the information collection.

4. Efforts to Identify Duplication and Use of Similar Information

Although we administer a number of user fee programs, this information collection specifically supports user fees associated with our generic drug program.

5. Impact on Small Businesses or Other Small Entities

The information collection imposes no undue burden on small entities. User fees are assessed in accordance with GDUFA II. To assist respondents in understanding user fees associated with generic drug applications we have developed the draft guidance document entitled, "*Assessing User Fees Under the Generic Drug User Fee Amendments of 2017.*"

The guidance explains the various fee assessments, procedures for payments and refunds, as well as other topics. The guidance is available on our internet at <https://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM593422.pdf> along with other information relating to implementation of GDUFA.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements, as well as timeframes agreed to in our current GDUFA commitment letter negotiated with industry. Potential or actual human generic drug application holders are required to complete submit a cover sheet for each abbreviated new drug application (ANDA), applicable amendment to an ANDA or a PAS, backlog ANDA, and other specified submissions. A generic drug facility identified or intended to be identified in at least one generic drug submission pending or approved to produce a final dosage form of a human generic drug or an API contained in a human generic drug is required to complete and submit a cover sheet annually.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5(d)(2)

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 the Federal Register of November 19, 2021 (86 FR 64945), we published a 60-day notice requesting public comment on the collection of information. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of the information submitted is protected under 21 CFR 314.430 and under 21 CFR part 20 and information will be handled consistent with these regulations. Additionally, the unauthorized use or disclosure of trade secrets that are required in applications is specifically prohibited under section 310(j) of the FD&C Act.

11. Justification for Sensitive Questions

The information collection does not include questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

Form FDA 3794	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Generic Drug User Fee Cover Sheet	500	7.616	3,808	0.5 (30 minutes)	1,904

We base our estimate on the average number of submissions received since last OMB review of the information collection, retaining the currently approved burden.

12b. Annualized Estimated Cost Burden Estimate

The estimated annual costs to respondents for all applicable applications and fees is \$87,584. 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.

13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

Costs of the information collection are absorbed through payment and administration of associated user fees.

15. Explanation for Program Changes or Adjustments

Although we have retained the currently approved burden estimate, we have revised the collection to include our current GDUFA performance goals. We are currently engaged in outreach activities with regard to reauthorization of user fees, and will revise and/or modify the information collection as necessary upon finalization.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for publication of the information received and therefore no associated tabulation or time schedules.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB control number as required by 5 CFR 1320.5 (and 21 CFR 1320.8(b)(1)); however, because documents are more frequently being accessed

electronically we are considering technological changes that will enable us to display the expiration date by linking to approval information found at www.reginfo.gov. We intend to include the OMB control number and expiration date on the guidance landing page, allowing those who download the document an easily identifiable option to view this information. This also allows the agency to more easily update the expiration date upon renewal and/or revision of OMB approval. We are taking this approach to improve compatibility with our current website platform (Drupal).

18. Exceptions to the Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.