UNITED STATES FOOD & DRUG ADMINISTRATION

Generic Drug User Fee Program

OMB Control Number 0910-0727 - Revision

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. Regulations applicable to the submission of abbreviated drug applications are found in 21 CFR part 314, subpart C. 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 2023-2027*,” available for download from our website at <https://www.fda.gov/media/153631/download>. Since its initial enactment in 2012, GDUFA has undergone a number of reauthorizations, most recently on September 30, 2022, under the FDA Generic Drug User Fee Act Reauthorization (GDUFA III). 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,

issued consistent with our Good Guidance Practice regulations found in 21 CFR 10.115 which provide for public comment at any time, and consistent with current GDUFA performance goals.

* The guidance documents, “*Controlled Correspondence Related to Generic Drug Development,” (*December 2022*)*” and “*Cover Letter Attachments for Controlled Correspondence and ANDA Submissions*,” (June 2023), provide information regarding the process by which generic drug manufacturers and related industry or their representatives can submit to FDA controlled correspondence requesting information related to generic drug development. The *Controlled Correspondence* guidances explain types of controlled correspondence, provide procedural recommendations on information to be included in controlled correspondence submitted to FDA, and explain how to request FDA clarification of responses to a controlled correspondence. The *Attachments* guidance clarifies that cover letter attachments have been designed as a checklist to reflect common types of information applicants are expected to address in their cover letters.
* To help support implementation of the CREATES Act, enacted as part of the Further Consolidated Appropriations Act of 2020 (Public Law 116-94), we issued the guidance document, “*How to Obtain a Covered Product Authorization,*” (September 2022 - DRAFT). The CREATES Act establishes a pathway for eligible generic drug product developers to obtain samples of brand products needed to support their applications and includes submissions to request covered product authorizations (CPAs). The *CPA Guidance* includes instructions that generic drug CPAs be submitted as complex controlled correspondence for an ANDA.

Finally, we have developed and utilize **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, and associated guidance documents 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. Guidance documents are intended to serve both as a useful guide to help applicants prepare their cover letters and to assist FDA in managing and facilitating submissions.

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.

Sponsors seeking FDA’s response to a controlled correspondence by the goal dates articulated in the GDUFA III *Commitment Letter* should submit the correspondence electronically through the NextGen Collaboration portal, which can be accessed at <https://edm.fda.gov>. This facilitates prompt consideration of and response to the controlled correspondence by the appropriate discipline staff. Requestors should register a corporate email address in the portal. We do not intend to consider portal submissions that are generated from general, personal accounts as controlled correspondence. If a requestor would like to obtain a secure email account, a requestor (or its U.S. agent) may apply for a secure email pathway by contacting secureemail@fda.hhs.gov.

4. Efforts to Identify Duplication and Use of Similar Information

Upon review of our current collection inventory we note related activity in OMB control nos. 0910-0191, where we cover general meeting and correspondence submissions, as well as other user fee programs. FDA notes that this collection is intended to cover those activities related and attributable to generic drug user fee submissions, including associated correspondence.

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection imposes undue burden on small entities; however, we provide resources to respondents and potential respondents to the information collection at <https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments>.

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 January 14, 2025, (89 FR 3225), we published a 60-day notice requesting public comment on the collection of information. Two comments were received, one pertaining to product pricing and the other pertaining to plant-based ingredients. FDA communicated it appreciates these public comments in its 30D-notice of 5/1/25; however, neither is responsive to the four information collection topics solicited under 5 CFR 1320.8(d) and therefore were discussed in the notice. We have made no adjustments in our estimated burden in response to the public comment.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

*The Privacy Act of 1974*

In preparing this supporting statement we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although the ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals’ professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted via **Form FDA 3794** (Generic Drug User Fee Cover Sheet) is point of contact name, business address, business telephone number, and business email address. We have determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

*The Freedom of Information Act (FOIA)*

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

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. 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 Burden1

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Information Collection; Activity | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
| Submission of Generic Drug User Fee Cover Sheet | 500 | 7.616 | 3,808 | 0.5(30 minutes) | 1,904 |
| Submission of Controlled Correspondence as Discussed in Agency Topic-Specific Guidance Documents  | 400 | 12.5 | 5,000 | 5 | 25,000 |
| Total |  |  | 8,808 |  | 26,904 |

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

Our estimated is based on available Agency data. Our burden estimate reflects an overall increase attributable to the inclusion of controlled correspondence and new generic drug product CPA requests. We also report more detailed information on submissions at <https://www.fda.gov/industry/generic-drug-user-fee-amendments/generic-drugs-program-monthly-and-quarterly-activities-report>.

 *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

We estimate no capital costs, or operating and maintenance costs, to be associated with the collection of information.

14. Annualized Cost to the Federal Government

Although significant costs of the information collection are absorbed through payment and administration of associated user fees and fee types, including those for Abbreviated New Drug Applications (ANDAs), Drug Master Files (DMFs), and facility fees. These fees and other appropriations supported 2,317 full-time equivalents, including salaries and operational expenses, to support human generic drug activities, where we estimate 613,000,000 in costs to FDA.

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.

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](http://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.

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