UNITED STATES FOOD & DRUG ADMINISTRATION

Generic Drug User Fee Program

OMB Control Number 0910-0727; Extension

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports the Food and Drug Administration's (FDA) Generic Drug User Fee Program. On July 9, 2012, the FDA Safety and Innovation Act (FDASIA) (Pub. L. 112-144) was signed into law. Title III of FDASIA established the Generic Drug User Fee Amendments (GDUFA), designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. Section 744B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379f, et seq.), as added by GDUFA, authorized FDA to assess and collect the fees related to generic drugs, beginning fiscal year (FY) 2013 and expiring at the close of FY 2017 on September 30, 2017. GDUFA was reauthorized on August 18, 2017 (GDUFA II), and is effective beginning October 1, 2017, through September 30, 2022. GDUFA II enables us to assess industry user fees to bring greater predictability and timeliness to the review of generic drug applications. Performance goals associated with GDUFA II are set forth in our commitment letter, which is available from our internet site at https://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM525234.pdf.

To assist respondents to the information collection we have developed Form FDA 3794 entitled, "*Generic Drug User Fee Cover Sheet*," which is completed and submitted electronically, and available at https://www.ipqpubs.com/wp-content/uploads/2012/09/GDUFA-cover-sheet.pdf, along with instruction at https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm322676.pdf. We have also developed a "*Generic Drug User Fee Amendments*" implementation activities page on our internet site that includes agency guidance and other resources intended to assist respondents with understanding the content and format requirements for GDUFA submissions, as well as understanding fee determinations, refunds, waivers, and other related topics.

We therefore request approval of the information collection provisions associated with implementation of GDUFA II, 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

Respondents create and/or submit Form FDA 3794 (*Generic Drug User Fee Cover Sheet*) electronically by accessing the User Fee System. 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 FDA administers 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 II.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is determined by respondents. Potential or actual human generic drug application holders are required to complete the proposed form for each

abbreviated new drug application (ANDA), 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, and new contract manufacturing organizations. 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 a final dosage form 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 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 September 25, 2018 (83 FR 48430), we published a 60-day notice requesting public comment on the collection of information. One comment was received asking whether the information was "*essential for FDA to conduct its duties*," and whether "t*here is a way to reduce burden*" on respondents. As discussed in both the 60-day notice and this notice, the information collection implements statutory provisions FDA must fulfill under GDUFA II. The information requested from respondents on Form FDA 3794 represents what we consider to be the minimum necessary for us to efficiently and electronically assess, collect, and track user fees associated with generic drug applications.

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

There are no questions of a sensitive nature associated with the information collection.

12. Estimates of Annualized Burden Hours and Costs

We estimate the burden of the collection of information as follows:

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.

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

We estimate annual costs to the Federal government in the amount of $87,584 for the administration of applicable applications and fees. These costs are based on staff allocations assuming a pay rate for a grade GS 12-5 employee. The estimate includes time and activities associated with the support, review, data entry, and tracking of submissions. The estimated hourly pay rate includes benefits but not overhead costs.

15. Explanation for Program Changes or Adjustments

The information collection reflects adjustments. Specifically, we have increased our estimate by **266** responses and **133** hours, consistent with an increase in submissions over the past three years.

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

Display of the OMB Expiration Date is appropriate.

18. Exceptions to the Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.