4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-5890]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Drug User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with our generic drug user fee program.

DATES: Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2024-N-5890 for "Generic Drug User Fee Program." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each

collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Generic Drug User Fee Program;

OMB Control Number 0910-0727--Revision

This information collection helps support implementation of FDA's Generic Drug User Fee Program (GDUFA), most recently reauthorized September 30, 2022. It includes information collections discussed in the document, "GDUFA Reauthorization Performance Goals And Program Enhancements Fiscal Years 2023-2027," commonly referred to as the "Goals Letter" or "Commitment Letter." The Commitment Letter represents the product of FDA discussions with the regulated industry and public stakeholders, as mandated by Congress. The Goals Letter identifies current GDUFA program objectives and general procedures for communicating with FDA. Agency guidance, as outlined in the Goals Letter, are utilized in the information

collection. All Agency guidance documents are issued consistent with our Good Guidance Practice regulations (21 CFR 10.115), which provide for public comment at any time, as well as regulatory authority found in 21 CFR 314.445 (Guidance documents), currently approved in OMB control number 0910-0001.

The information collection also includes Form FDA 3974, the Generic Drug User Fee Cover Sheet and associated instructions, available for download at https://userfees.fda.gov/OA_HTML/GDUFAFacilityCScreation.pdf. Form FDA 3974 is used 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.

As we communicate on our website, potential applicants are encouraged to contact the FDA Generic Drugs Program with questions at any point in their development and application preparation processes. We have revised the information collection to include the submission of "controlled correspondence" within the scope of activity, including covered product authorizations (CPAs) provided for under the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (CREATES Act) (Pub. L. 116-94). Historically, and under the terms of the GDUFA, a controlled correspondence may be submitted by or on behalf of a generic drug manufacturer or related industry prior to submitting an abbreviated new drug application (ANDA). To provide respondents with assistance regarding the submission of controlled correspondence, we continue to develop and issue topic-specific Agency guidance, including the following documents:

- Controlled Correspondence Related to Generic Drug Development (Controlled Correspondence Guidance), (https://www.fda.gov/media/164111/download, March 2024)
- Product-Specific Guidance Meetings Between FDA and ANDA Applicants Under GDUFA, (https://www.fda.gov/regulatory-information/search-fda-guidance-

documents/product-specific-guidance-meetings-between-fda-and-anda-applicants-under-gdufa, February 2023)

- Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-fda-and-anda-applicants-complex-products-under-gdufa-guidance-industry, October 2022)
- Competitive Generic Therapies Guidance (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/competitive-generic-therapies, October 2022)
- Cover Letter Attachments for Controlled Correspondences and ANDA Submissions (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cover-letter-attachments-controlled-correspondences-and-anda-submissions, June 2023)
- How to Obtain Covered Product Authorization (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-obtain-covered-product-authorization, September 2022)

Each guidance document may be downloaded from our website where we maintain a searchable database at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

FDA estimates the burden of the information collection as follows:

Table 1: Estimated Annual Reporting Burden[1]

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	5000	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.

Dated: January 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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