



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Drug User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review--Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0727. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Drug User Fee Program

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>.

In the *Federal Register* of January 14, 2025 (90 FR 3225), we published a 60-day notice soliciting comment on the proposed collection of information. Two comments were received, one pertaining to product pricing and the other pertaining to plant-based ingredients. FDA appreciates these public comments; however, neither is responsive to the four information collection topics solicited under 5 CFR 1320.8(d) and therefore not discussed in this notice. We have made no adjustments in our estimated burden in response to the public comment.

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

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.

Dated: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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