

UNITED STATES FOOD & DRUG ADMINISTRATION

OMB Control Number 0910-0727; Generic Drug User Fee Program

Request for Non-substantive change:

The information collection in OMB control number 0910-0727 supports implementation of FDA's Generic Drug User Fee program. "GDUFA" authorizes FDA to assess and collect 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. To help achieve these objectives, we employ specific program and performance goals as outlined in a Commitment Letter. The Commitment Letter is developed with respondents and updated with each statutory reauthorization to include progressive enhancements that facilitate the delivery of safe and effective generic drugs to the public and help reduce costs to industry. We provide information regarding GDUFA and ongoing implementation on our website at <https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments>, including the most recently authorized Commitment Letter.

For operational efficiency, we are requesting to account for burden that may be attendant to the submission of controlled correspondence, previously approved in OMB control number 0910-0797. As we communicate in Section I (*Submission Assessment Performance Goals*), Subsection E (*Controlled Correspondence*) of our Commitment Letter and on our website, a *controlled correspondence* is a communication submitted to FDA by or on behalf of a generic drug manufacturer or related industry requesting information on a specific element of generic drug product development, or certain post-approval submission requirements. Relatedly, and again for operational efficiency, we are requesting to account for burden that may be attendant to the submission of information associated with Covered Product Authorization Requests (CPAs). CPAs are considered controlled correspondence and are provided for under the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (CREATES Act) to provide a pathway for eligible product developers to obtain access to the product samples they need to fulfill testing and other regulatory requirements to support applications. To make use of this pathway, an eligible product developer must obtain a CPA (see 21 U.S.C. 355-2(b)(2)).

To provide respondents with instructional information including format and content considerations regarding the submission of controlled correspondence under GDUFA, we continue to develop and issue agency guidance documents. We believe the guidance documents are issued in accordance with our regulatory authority in 21 CFR 314.445 (*Guidance documents*), which we discuss in our supporting statement for OMB control number 0910-0001. We believe the guidance documents are also issued consistent with our currently authorized Commitment Letter and with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. We have added the information collection element, "*Submission of Controlled Correspondence*," to account for burden that may be attendant to recommendations found in the respective guidance documents:

- [Product-Specific Guidance Meetings Between FDA and ANDA Applicants Under GDUFA](#) (February 2023)

- [Controlled Correspondence Related to Generic Drug Development Guidance for Industry: Draft Guidance for Industry](#) (December 2020)
- [Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA](#) (October 2022)
- [Competitive Generic Therapies Guidance](#) (October 2022)
- [Cover Letter Attachments for Controlled Correspondences and ANDA Submissions](#) (June 2023)
- [How to Obtain Covered Product Authorization](#) (September 2022)

Specifically we have added 5,000 responses and 25,000 hours annually to reflect the submission of controlled correspondence to FDA. Because the information collection recommendations found in the guidance documents are currently utilized to help us adhere to timeframes for review as committed to in our user fee authority, we request to include them with related activities here.

Submitted: October 2023