

UNITED STATES FOOD & DRUG ADMINISTRATION

Biosimilar User Fee Program

OMB Control Number 0910-0718 – REVISION

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports the Food and Drug Administration’s (FDA, us or we) Biosimilars User Fee Program (BsUFA) and implementation of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The BPCI Act amended the Public Health Service Act (PHS Act) by adding section 351(k) (42 U.S.C. 262(k)) to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Section 351(k) defines biosimilarity to mean “*that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components*” and that “*there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.*” A 351(k) application must contain, among other things, information demonstrating that the biological product is biosimilar to a reference product based upon data derived from analytical studies, animal studies, and clinical studies, unless FDA determines, in its discretion, that certain studies are unnecessary in a 351(k) application. Section 351(k) of the PHS Act (42 U.S.C. 262(k)), sets forth the requirements for an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product. We maintain information on our website at <https://www.fda.gov/industry/fda-user-fee-programs/biosimilar-user-fee-amendments> regarding our BsUFA program to provide interested persons with updates on related deliverables and activities. We also communicate key actions the agency is taking to encourage innovation, development, and competition among biologics and the development of biosimilars, and builds on progress in implementing the approval pathway for biosimilar and interchangeable products.

We have revised the information collection to reflect the currently agreed-upon performance goals established and captured in the latest reauthorization document entitled, “*Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027*” (BsUFA Commitment Letter). The BsUFA Commitment Letter is available for download from our website at <https://www.fda.gov/media/152279/download?attachment>. The BsUFA Commitment Letter outlines current program goals, including information technology goals, discusses program effectiveness considerations, and discusses user fee resource management.

The information collection utilizes agency forms. FDA is authorized to assess and collect Biosimilar Biological Product Fees under section 744H of the Federal Food, Drug, and Cosmetic Act (FFDCA) and in connection with biosimilar biological product development (BPD). Form FDA 3792, entitled “*Biosimilars User Fee Cover Sheet*,” is submitted by respondents and

requests the minimum necessary information to identify the request and determine the amount of the fee to be assessed, and to account for and track user fees. The form provides a cross-reference of the fees submitted for an activity with the actual submission or activity by using a unique number tracking system. Form FDA 3971 (Small Business Waiver and Refund Request), currently approved in OMB control no. 0910-0297, may also be utilized in this collection of information. As instructed on our BsUFA webpage, respondents should submit Form FDA 3971 by e-mail to CDERCollections@fda.hhs.gov at least four months prior to the submission of the application to see if they qualify for a small business waiver. Finally, user fee refund and transfer requests, currently approved in OMB control no. 0910-0805, may be submitted to FDA using Forms FDA 3913 and FDA 3914, respectively.

Patent infringement notifications are also included in the scope of collection activity. Section 351(l) of the PHS Act (42 U.S.C. 242(l)) provides for the exchange of patent information and resolution of patent disputes between a 351(k) biosimilar applicant and the holder of the 351(a) BLA reference product. If a biosimilar applicant is served with a complaint in an action for a patent infringement as described in section 351(l)(6) of the PHS Act, the biosimilar applicant is required to provide the Secretary of HHS with notice and a copy of the complaint within 30 days of service. FDA is required to publish notice of a complaint received under section 351(l)(6)(C) of the PHS Act in the Federal Register.

Relevant information regarding applicable statutory requirements is discussed in topical guidance documents, issued consistent with our BsUFA Commitment Letter and Agency Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. The following draft and final guidance documents include instructional and procedural information on communicating with FDA regarding the BsUFA program:

- “Assessing User Fees Under the Biosimilar User Fee Amendments of 2022” (July 2023), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-user-fees-under-biosimilar-user-fee-amendments-2022>. The guidance document instructs respondents on requesting discontinuation from the BPD program, as well as requesting to move products to the discontinued section of the biosimilar list. The guidance document also provides information on the consequences of failing to pay BsUFA III fees as well as processes for submitting reconsideration and appeal requests.
- “Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products” (August 2023), available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-fda-and-sponsors-or-applicants-bsufa-products-guidance-industry>. The guidance document explains standardized procedures for requesting, preparing, scheduling, conducting, and documenting formal meetings with FDA, and discusses good meeting management practices.
- As listed on our CDER 2023 and [2024 Annual Guidance](#) agendas, we are planning to issue a draft guidance for industry entitled “Pediatric Study Plans for Biosimilar Products,” to help implement provisions of the Pediatric Research Equity Act

(PREA), codified in section 505B of the FD&C Act (21 USC 355c). For more information regarding FDA guidance documents, including ways to participate, please visit <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>.

We therefore request OMB approval of the information collection provisions authorized under the Biosimilar User Fee provisions of the FFDCA, Form FDA 3792, and information collection discussed in the referenced guidance documents included in this supporting statement.

2. Purpose and Use of the Information Collection

The information collection is used to support FDA's BsUFA program, whereby user accounts are established, fees are assessed, monitored, tracked, and refunded as appropriate. The program fulfills our Congressional mandate to administer and maintain provisions set forth under the BPCI Act as well as the most reauthorization for BsUFA II. Respondents to the information collection are sponsors and/or applicants who have submitted, or intend to submit, an application for a biosimilar product for licensure under section 351(k) of the PHS Act, or who intend to submit an iPSP as described in section 505B(e) for those products intended to be licensed under section 351(k) of the Public Health Service Act.

3. Use of Improved Information Technology and Burden Reduction

Electronic submissions are encouraged throughout FDA and BsUFA II development participants are required to electronically file their applications. We estimate that 99% of the respondents will use electronic means to fulfill the regulatory requirements and information requests. Fee payments are collected and recorded electronically.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We believe the information collection imposes no undue burden on small entities. Fees are assessed in accordance with schedules established by statute and certain small business waivers may apply. At the same time, we provide assistance to small businesses through our Center for Biologics Evaluation and Research (CBER) Office of Communications, Outreach and Development, Division of Manufacturer's Assistance and Training; and our Center for Drug Evaluation and Research (CDER) Office of Communication, Division of Drug Information.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with applicable statutory and regulatory requirements, as well as agreed upon performance goals negotiated with respondents. Application submissions are made at the initiation of respondents. There are no legal obstacles to reducing burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

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 accordance with 5 CFR 1320.8(d), we published a 60-day notice in the *Federal Register* of September 23, 2024 (89 FR 77531), requesting public comment on the proposed collection of information. No comments were received. In accordance with 5 CFR 1320.5(a)(1)(vi), a 30-day notice is scheduled for publication in the *Federal Register* on February 3, 2025, having been inadvertently delayed due to unforeseen circumstances. Because the information collection activity covers a statutory critical public health program, we obtained OMB permission to submit the ICR in advance of this date. OMB has not waived publication requirements under 5 CFR 1320.5(a)(1)(iv).

9. Explanation of Any Payment or Gift to Respondents

No gifts or payments are provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

In preparing this supporting statement, we consulted FDA's Privacy Office to ensure appropriate identification and handling of information collected. Although this 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 3792** (Biosimilar User Fee Cover Sheet) is business 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 and webpage 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 makes 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.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature applicable to this collection of information.

12. Estimates of Annualized Burden Hours and Costs

12a. *Annualized Hour Burden Estimate*

Table 1.--Estimated Annual Reporting Burden

FDA Form; Survey	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Biosimilar User Fee Cover Sheet (Form FDA 3792)	30	2	60	0.5 (30 minutes)	30
Request for discontinuation from BPD program or to move products to discontinued section of Biosimilar List	6	1	6	1	6
Biosimilar product & interchangeable product applications (351(k)); patent infringement notifications (351(l))	16	1.94	31	610.90	18,938
Formal meeting requests as recommended in FDA guidance	135	2.30	311	21.42	6,661
Submission of Pediatric Assessment; iPSP template information, including deferrals of pediatric assessments for proposed biosimilar products; iPSP amendments as recommended in FDA guidance	11	1	11	38.18	420
Total			419		2605526055

12b. *Annualized Cost Burden Estimate*

Our cost estimate assumes the hourly wage rate for a *regulatory affairs specialist* of \$90.70/hour based on data found in the Department of Labor's National Industry-Specific Occupational Employment and Wage Estimates for Pharmaceutical and Medicine Manufacturing (NAICS, code 325400) category. We assume no overhead costs, and multiply the total annual number of burden hours (26,055), to calculate an annual cost of \$2,368,188.50.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

We assume an allocation of 4.1 FTEs to cover issuing invoices and to the review of and response to requests for waivers, reductions, and refunds for biosimilars. We exclude costs covered by program fees from our calculations. Assuming each FTE costs \$336,269, (including overhead), we calculate a cost to the Federal Government of \$1,378,703.

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15. Explanation for Program Changes or Adjustments

The information collection reflects an increase of 13,069 hours and 105 responses annually. Although part of the increase accounts for burden associated with respondents including the submission of pediatric study plan information, the majority of adjustments correspond with an increase in submissions we are receiving under BsUFA.

16. Plans for Tabulation and Publication and Project Time Schedule

We do not intend to publish tabulated results of these information collection requirements.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

As required by the PRA and consistent with established agency practice, FDA will publish a notice in the Federal Register announcing OMB approval of information collection associated with guidance documents included in this information collection. The notice will inform respondents of the OMB control number and current expiration date. However, because agency guidance documents are more frequently being accessed electronically, we are making technological updates to display the expiration date by linking to approval information found at <https://www.reginfo.gov/public/>. We intend to include the OMB control number and expiration date on the guidance document 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 of associated information collection. We are taking this approach to improve compatibility with current website platforms utilized by FDA.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.