**4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2018-N-1967]**

# Agency Information Collection Activities; Proposed Collection; Comment Request; Biosimilars User Fee Program

**AGENCY:** Food and Drug Administration, Health and Human Services (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 the Agency's Biosimilars User Fee Program.

**DATES:** Submit either electronic or written comments on the collection of information 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. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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 postmarked or the delivery service acceptance receipt is 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-2018-N-1967 for "Biosimilars 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.

Biosimilars User Fee Program

OMB Control Number 0910-0718--Revision

This information collection supports FDA's Biosimilars User Fee Program. The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) amended the Public Health Service Act (PHS Act) 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) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, allows a company to apply for licensure of a biosimilar or interchangeable biological product (351(k) application).

The BPCI Act also amended section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) to include 351(k) applications as a type of application under "human drug application" for the purposes of the prescription drug user fee provisions.

The Biosimilar User Fee Act of 2012 (BsUFA) authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development (BPD). BsUFA was reauthorized for an additional 5 years in August 2017 (BsUFA II). We developed the guidance entitled "Assessing User Fees Under the Biosimilar User Fee Amendments of 2017" to assist industry in understanding when fees are incurred and the process by which applicants can submit payments. The guidance also explains how respondents can request discontinuation from the BPD program as well as how respondents can request to move products to the discontinued section of the biosimilar list. Finally, the guidance provides information on the consequences of failing to pay BsUFA II fees as well as processes for submitting reconsideration and appeal requests. The guidance is available on the FDA website at: https://www.fda.gov/media/134567/download. The guidance was issued consistent with our Good Guidance Practice regulations in § 10.115 (21 CFR 10.115), which provide for public comment at any time.

We also developed Form FDA 3792, the Biosimilars User Fee Cover Sheet, which is submitted by each new BPD entrant (identified via a new meeting request or investigational new drug (IND) submission) and for new biologics license applications (BLAs). Form FDA 3792 requests the minimum necessary information to identify the request, to 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. The information collected is used by FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research to initiate the administrative screening of biosimilar biological product INDs and BLAs and to account for and track user fees associated with BPD meetings.

In addition to Form FDA 3792, the information collection includes an annual survey of all BsUFA II participants designed to provide information to FDA of anticipated BsUFA II activity in the upcoming fiscal year. This information helps FDA set appropriate annual BsUFA II fees.

For efficiency of Agency operations, we are consolidating related information collection currently approved in OMB control number 0910-0719. Specifically we are including our current commitment goals as set forth in the document "BsUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022," which represents the product of FDA discussions with regulated industry and public stakeholders, as mandated by Congress. The document, referred to as the "BsUFA II letter," is available on our website at: https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf. The performance and procedural goals specified in the BsUFA II letter apply to aspects of the biosimilar biological product review program that are important for facilitating timely access to safe and effective biosimilar medicines for patients. Among those considerations is providing feedback to requests from regulated industry. Each year, FDA review staff participate in many meetings with requesters who seek advice relating to the development and review of a biosimilar or interchangeable product. Because these meetings often represent critical points in the regulatory and development process, it is important that there are clear procedures for the timely and effective conduct of such meeting. Accordingly, we issued draft guidance, "Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products," available on our website 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 was issued consistent with Section I, Part 6 of the BsUFA II letter (see p. 25), and with our Good Guidance practice regulations in § 10.115, which provide for public comment at any time. The guidance provides procedural instruction helpful to respondents and helps us reach what we believe is a more accurate burden estimate for the information collection.

Also available from our website is our Biosimilars Action Plan (BAP), which discusses key actions the Agency is taking to encourage innovation and competition among biologics and the development of biosimilars. The BAP builds on progress in implementing the approval pathway for biosimilar and interchangeable products, and provides interested persons with updates and resource material.

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

Table 1.--Estimated Annual Reporting Burden

| FDA Form; Survey | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response (Hours) | Total Hours |
|---|---|---|---|---|---|
| Biosimilar User Fee Cover Sheet (Form FDA 3792) | 60 | 1 | 60 | 0.5 (30 minutes) | 30 |
| Annual Survey | 60 | 1 | 60 | 1 | 60 |
| Request for discontinuation from BPD program | 10 | 1 | 10 | 1 | 10 |
| Request to move products to discontinued section of the Biosimilar List | 5 | 1 | 5 | 0.5 (30 minutes) | 2.5 |
| Biosimilar product applications (351(k)(2)(A)) | 4 | 2.25 | 9 | 860 | 7,740 |
| Interchangeable product applications (351(k)(2)(B) | 2 | 1 | 2 | 860 | 1,720 |
| Patent infringement notifications | 4 | 2.25 | 9 | 2 | 18 |
| Formal Meetings GFI Recommendations | 69 | 2.30 | 159 | 21.42 | 3,405 |
| Total | | | 314 | | 12,985.5 |

In anticipation of increased participation in the BPD program, we have increased our estimate to reflect an increase in the number of respondents since last OMB review. We have also made adjustments to reflect information collection consolidated from OMB control number 0910-0719. We invite comment on our estimates and assumptions.

Dated: September 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-20060 Filed: 9/16/2021 8:45 am; Publication Date: 9/17/2021]