to reflect a resulting increase of 114 hours and 94 responses annually.

Dated: September 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21676 Filed 9–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4146]

Agency Information Collection Activities; Proposed Collection; Comment Request; Biosimilars 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 the Agency's Biosimilars User Fee Program.

DATES: Either electronic or written comments on the collection of information must be submitted by November 22, 2024.

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 November 22, 2024. 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–4146 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; 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 revision 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 and implementation of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The BPCI Act creates 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 Public Health Service Act (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 (FD&C 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 FD&C Act as amended by the Biosimilar User Fee Amendments of 2022 (BsUFA III), reauthorizes FDA to assess and collect fees for biosimilar biological products from October 2022 through September 2027 to facilitate the development of safe and effective biosimilar products for the American public.

FDA maintains information on our website at *https://www.fda.gov/industry/fda-user-fee-programs/biosimilar-user-fee-amendments* regarding FDA's BsUFA program. Also available on our website is the 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 on related deliverables and activities.

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 also includes Form FDA 3792, ''Biosimilars User Fee Cover Sheet,'' to be submitted by each new biological product development (BPD) entrant (identified via a new meeting request or investigational new drug (IND) submission) or new biologics license application (BLA) applicant. Form FDA 3792 requests the minimum information necessary to identify the request, to determine the amount of the fee to be assessed, and to account for and track user fees. Form FDA 3792 is completed electronically at *https://userfees.fda.gov/OA_HTML/bsufaCAcdLogin.jsp,* and a notification is emailed to the respondent that includes information regarding annual program fees. We are discontinuing use of the associated annual survey at this time.

Relatedly, Form FDA 3971 (Small Business Waiver and Refund Request), currently approved in OMB control number 0910–0297, may also be utilized. As instructed on our BsUFA web page, respondents should submit Form FDA 3971 by email to *CDERCollections@fda.hhs.gov* at least 4 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 number 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 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 agenda, 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, codified in section 505B of the FD&C Act (21 U.S.C. 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.*

Description of Respondents: Sponsors and applicants who have 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 initial pediatric study plan (iPSP) as described in section 505B(e)

for those products intended to be licensed under section 351(k) of the PHS Act and being developed as a proposed biosimilar to a reference product.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

FDA form; survey	Number of respondents	Number 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		26,055

Our estimated burden for the information collection reflects an overall increase of 13,069 hours and 105 responses annually. Although part of the increase may be attributed to the inclusion of burden associated with the submission of pediatric study plans, we regard the majority of adjustments as nominal fluctuations consistent with the number of applications and submissions we are receiving.

Dated: September 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21671 Filed 9–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Adult Lifespan Psychopathology Study Section.

Date: October 17–18, 2024.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Benjamin G. Shapero, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7848, Bethesda, MD 20892, (301) 402–4786, *shaperobg@mail.nih.gov*.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Gene Regulation in Cancer Study Section.

Date: October 21–22, 2024.

Time: 9:30 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Manzoor A. Zarger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6208, MSC 7804, Bethesda, MD 20892, (301) 435–2477, *zargerma@csr.nih.gov*.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Biobehavioral Regulation, Learning and Ethology Study Section.

Date: October 21–22, 2024.

Time: 9:30 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Sara Louise Hargrave, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 3170, Bethesda, MD 20892, (301) 443–7193, *hargravesl@mail.nih.gov*.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Basic Cancer Immunobiology Study Section.

Date: October 22–23, 2024.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Meeting Format: In Person.

Contact Person: Sarita Kandula Sastry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20782, 301–402–4788, *sarita.sastry@nih.gov*.

Name of Committee: Applied Therapeutics for Cancer Integrated Review Group; Mechanisms of Cancer Therapeutics C Study Section.

Date: October 22–23, 2024.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Darcy Hotel, 1515 Rhode Island Ave, NW, Washington, DC 20005.

Meeting Format: In Person.

Contact Person: Gloria Huei-Ting Su, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–496–0465, *gloria.su@nih.gov*.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Muscle and Exercise Physiology Study Section.

Date: October 22–23, 2024.

Time: 8:00 a.m. to 10:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Meeting Format: In Person.

Contact Person: Carmen Bertoni, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 805B,