intends to consider those comments. Please submit any additional comments regarding the guidances that you wish the Agency to consider, including whether it would be appropriate to reissue these guidances in draft form or consider a later implementation date.

II. Paperwork Reduction Act of 1995

While these guidance documents contain no collection of information, they do refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR 1271 relating to HCT/Ps, including establishing and maintaining records, investigation and reporting of adverse actions and documentation of methods used in facilities related to HCT/Ps, which, includes but is not limited to donor screening, donor testing, and labeling have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the internet may obtain the guidances at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dorothy A. Fink,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2025–02167 Filed 1–31–25; 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; Submission for Office of Management and Budget Review; Comment Request; Biosimilars User Fee Program

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 March 5, 2025.

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 0910–0718. 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.

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 its 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 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 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 Center for Drug Evaluation and Research 2023 and 2024 Annual Guidance agenda (available at: *https://www.fda.gov/media/134778/download*), 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) of the FD&C Act 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.

In the **Federal Register** of September 23, 2024 (89 FR 77531), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this information collection 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, the majority of adjustments correspond with an increase in submissions we are receiving.

Dated: January 28, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–02153 Filed 1–30–25; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2803–25]

Vacatur of 2025 Temporary Protected Status Decision for Venezuela

AGENCY: U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security (DHS).