TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Number of respondents	Responses per respondent	Average burden hours per response (minutes)	Total burden hours
526	1	15	131.5

Dated: July 25, 2023.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2023–16015 Filed 7–27–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2757]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices—Voluntary Improvement Program

AGENCY: Food and Drug Administration, 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 August 28, 2023.

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 title of this information collection is ''Voluntary Improvement Program.'' 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.

Voluntary Improvement Program

OMB Control Number 0910–NEW

This information collection supports FDA's implementation of its Voluntary Improvement Program (VIP). Included among the strategic priorities of our Center for Devices and Radiological Health (CDRH) is promoting a culture of quality and organizational excellence. As communicated on our website at *https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/voluntary-medical-device-manufacturing-and-product-quality-pilot-program,* we conducted a pilot project pertaining to voluntary medical device manufacturing and product quality and have incorporated some of the successes and learnings into the VIP. The VIP oversees third-party appraisers who evaluate industry participants. The VIP is facilitated by the Medical Device Innovation Consortium, a public-private partnership that evaluates the capability and performance of a medical device manufacturer's practices using third-party appraisals and is intended to guide improvement to enhance the quality of devices. As part of the VIP process, FDA receives information about participating device manufacturers' capability and performance for activities covered in third-party appraisals.

The guidance document entitled ''Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program'' communicates our policy regarding participation in the VIP. Only eligible manufacturers of medical devices regulated by CDRH whose marketing applications are reviewed under the applicable provisions of the Federal Food, Drug, and Cosmetic Act (including under sections 510(k), 513, 515, and 520 (21 U.S.C. 360(k), 360c, 360e, and 360j)) may participate in the VIP. The guidance document was developed and issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time. The guidance document includes instruction to respondents regarding eligibility, FDA engagement with participants, submission criteria, and withdrawal or removal from the program.

Information included in VIP applications is verified by FDA. This helps the third-party appraiser to determine the manufacturers' eligibility for participation in the VIP. We use aggregate data to identify broad industry trends and patterns to help inform risk-based inspection planning and improve review efficiencies. We also consider aggregate data to better allocate limited Agency resources. Also included among the goals of the program is to improve the safety, quality, and access of medical devices for patients by driving quality and continuous improvement within the device industry. The program is intended to result in increased production and access to higher quality medical devices for patients, decreases in safety issues, and lower production costs, which will increase value to industry, patients, providers, payors, and FDA.

We published a 60-day notice soliciting public comment on the proposed collection of information in the **Federal Register** of May 6, 2022 (87 FR 27165) and received several comments. Most comments included feedback on individual collection elements and the operational logistics of the program. We have considered these comments. Although we intend to revise the guidance to clarify what participants must demonstrate to benefit from the opportunities offered by VIP and add further details regarding the role of FDA in VIP in section V.B of the guidance, we are making no adjustments to our burden estimates. In addition, two comments requested FDA clarify the benefits and utility of VIP for patients and consumers. FDA intends to address these comments in the guidance document, which guides improvement to enhance the quality of devices.

Respondents: Respondents to the information collection are manufacturing sites who voluntary elect to participate in the VIP. Based on our device registration and listing data and informal feedback from stakeholders, we anticipate approximately 400 sites may participate annually.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Recommended information collection activity: Fostering medical device improvement: FDA activities and engagement with the voluntary Improvement Program	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Site manufacturer application	1	400	400	0.08 (5 minutes)	33
Aggregate data reporting	1	4	4	8	32
Summary of site appraisal	1	400	400	20	8,000
Total					8,065

[1] There are no capital or operating and maintenance costs associated with the information collection.

Site Manufacturer Application

In section IV.A of the guidance, we explain that manufacturers wishing to apply for an appraisal may do so at the third-party appraiser's application portal. As part of the VIP process (see section IV.D, *Process Flow,* of the guidance), the site manufacturers' application information is provided to FDA by the third-party appraiser. We assume it will take the third-party appraiser approximately 5 minutes to notify FDA of the availability of each application. Such notification is provided via email and FDA may then access the information via the third-party appraiser's online portal.

Aggregate Data Reporting

As discussed in sections III and IV of the guidance, the third-party appraiser provides FDA with aggregated data across all participating manufacturer sites quarterly. We assume that it will take approximately 8 hours to prepare and submit the aggregate data.

Summary of Site Appraisal

In section IV.D of the guidance, we communicate that the third-party appraiser will provide FDA a summary of the appraisal result for each participating site. We assume an average of 20 hours is necessary to prepare and submit the summary.

This is a new information collection. Specifically, we are accounting for third-party appraiser burden to provide the site manufacturer's information to FDA under the VIP process. We believe associated recordkeeping by participating manufactures to be usual and customary business practice and have therefore not included estimates for VIP application activities by manufacturers. The estimated average burden per response is largely based on our experience with the program pilot and informal communications with participants.

Dated: July 25, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16079 Filed 7–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2966]

Biosimilar User Fee Rates for Fiscal Year 2024

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the rates for biosimilar user fees for fiscal year (FY) 2024. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Biosimilar User Fee Amendments of 2022 (BsUFA III), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development; review of certain applications for approval of biosimilar biological products; and each biosimilar biological product approved in a biosimilar biological product application. BsUFA III directs FDA to establish, before the beginning of each fiscal year, the amount of initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application and program fees for such year. These fees apply to the period from October 1, 2023, through September 30, 2024.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo (Funmi) Ariyo, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., 6th Floor, Beltsville, MD 20705–4304, 240–402–4989, and the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744G, 744H, and 744I of the FD&C Act (21 U.S.C. 379j–51, 379j–52, and 379j–53), as amended by BsUFA III, authorize the collection of fees for biosimilar biological products. Under section 744H(a)(1)(A) of the FD&C Act, the initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application or within 7 calendar days after FDA grants the first BPD meeting, whichever occurs first. A sponsor who has paid the initial BPD fee is considered to be participating in FDA's BPD program for that product.

Under section 744H(a)(1)(B) of the FD&C Act, once a sponsor has paid the initial BPD fee for a product, the annual BPD fee is assessed beginning with the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits a marketing application for the product that is accepted for filing, the sponsor discontinues participation in FDA's BPD program for the product, or the sponsor has been administratively removed from the BPD program for the product.

Under section 744H(a)(1)(D) of the FD&C Act, if a sponsor has discontinued participation in FDA's BPD program or has been administratively removed from the BPD program for a product and wants to reengage with FDA on development of the product, the sponsor must pay all annual BPD fees previously assessed for such product and still owed, and a reactivation fee to resume participation in the program. The sponsor must pay the reactivation fee by the earlier of the following dates: (1) no later than 7 calendar days after FDA grants the sponsor's request for a BPD meeting for that product or (2) upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product. The sponsor will be assessed an annual BPD