

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-2019]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Class II Special Controls: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Principle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 30, 2024.

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 0910-0594. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, 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.

Class II Special Controls: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle

OMB Control Number 0910-0594—Extension

This information collection helps to support Agency regulations and guidance. Under Section 513(a)(1)(B) of the Federal Food, Drug and Cosmetics Act (FD&C Act) (21 U.S.C. 360c(a)(1)(B)), FDA may establish special controls, including performance standards, postmarket surveillance, patient registries, guidelines, and other appropriate actions it believes necessary to provide reasonable assurance of the safety and effectiveness of the device. The guidance entitled “Guidance for Industry and FDA Staff—Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle” (March 2011) is available at <https://www.fda.gov/media/124263/download>. The special control guidance serves as the special control for the automated blood cell separator device operating by centrifugal or filtration separation principle intended for the routine collection of blood and blood components (§ 864.9245 (21 CFR 864.9245)).

For currently marketed products not approved under the premarket approval process, the manufacturer should file with FDA for 3 consecutive years an annual report on the anniversary date of the device reclassification from class III to class II or on the anniversary date of the 510(k) of the FD&C Act (21 U.S.C. 360(k)) clearance. These annual reports are submitted as supplements to the original 510(k) via the electronic submission gateway at <https://www.fda.gov/electronic-submissions-gateway>. The reports can also be submitted in paper format and sent to

the CBER Document Control Center at <https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/regulatory-submissions-electronic-and-paper>.

Any subsequent change to the device requiring the submission of a premarket notification in accordance with section 510(k) of the FD&C Act should be included in the annual report. Also, a manufacturer of a device determined to be substantially equivalent to the centrifugal or filtration-based automated cell separator device intended for the routine collection of blood and blood components should comply with the same general and special controls.

Reclassification of this device from class III to class II relieves manufacturers of the burden of complying with the premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e) and may permit small potential competitors to enter the marketplace by reducing the burden. Although the special control guidance recommends that manufacturers of these devices file with FDA an annual report for 3 consecutive years, this would be less burdensome than the current postapproval requirements under 21 CFR part 814, subpart E, including the submission of periodic reports under 21 CFR 814.84.

In the special control guidance document, FDA recommends that manufacturers include in their annual reports a summary of adverse reactions maintained by the blood collection establishment or transfusion service or similar reports of adverse events collected.

In the **Federal Register** of May 22, 2024, (89 FR 44991), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Recommended activity; guidance section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual Report; Section VI, Special Controls	3	1	3	5	15

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on submissions to FDA over the last few years, there are three manufacturers of automated blood cell separator devices. We estimate that the manufacturers will spend

approximately 5 hours preparing and submitting the annual report.

The annual report should include, at a minimum, a summary of anticipated and unanticipated adverse events that have occurred and that are not required

to be reported by manufacturers under Medical Device Reporting (MDR) (part 803 (21 CFR part 803)). The reporting of adverse device events summarized in an annual report will alert FDA to trends or clusters of events that might be a

safety issue otherwise unreported under the MDR regulation. The report should also include any subsequent change to the preamendments class III device requiring a 30-day notice in accordance with 21 CFR 814.39(f).

Blood collection establishments and transfusion services, the intended users of the device, and the device manufacturers have certain responsibilities under the Federal regulations. For example, collection establishments and or transfusion services are required to maintain records of any reports of complaints of adverse reactions (21 CFR 606.170), while the device manufacturer is responsible for conducting an investigation of each event that is reasonably known to the manufacturer and evaluating the cause of the event (§ 803.50(b) (21 CFR 803.50(b))). In addition, manufacturers of medical devices are required to submit to FDA individual adverse event reports of death, serious injury, and malfunctions (§ 803.50).

Other burden hours required for § 864.9245 are reported and approved under OMB control number 0910–0120 (premarket notification submission 510(k), 21 CFR part 807, subpart E), and OMB control number 0910–0437 (MDR, part 803).

Based on a review of the information collection from our last request for OMB approval, we estimate that the number of manufacturers of automated blood cell separator devices remains unchanged. As a result, we have made no adjustments to our burden estimates.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16831 Filed 7–30–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3382]

Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the fiscal year (FY) 2025 fee rates for certain domestic and foreign

facility reinspections, failures to comply with a recall order, and importer reinspections that are authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA).

DATES: These fees apply to the period from October 1, 2024, and will remain in effect through September 30, 2025.

FOR FURTHER INFORMATION CONTACT:

For questions related to FSMA program fees: FSMAFeeStaff@fda.hhs.gov.

For questions related to this notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240–402–4989; or the User Fees Support Staff at OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 107 of the FSMA (Pub. L. 111–353) added section 743 to the FD&C Act (21 U.S.C. 379j–31) to provide FDA with the authority to assess and collect fees from, in part: (1) the responsible party for each domestic facility and the U.S. agent for each foreign facility subject to a reinspection to cover reinspection-related costs; (2) the responsible party for a domestic facility and an importer who does not comply with a recall order to cover food¹ recall activities associated with such order; and (3) each importer subject to a reinspection to cover reinspection-related costs (sections 743(a)(1)(A), (B), and (D) of the FD&C Act). Section 743 of the FD&C Act directs FDA to establish fees for each of these activities based on an estimate of 100 percent of the costs of each activity for each year (sections 743(b)(2)(A)(i), (ii), and (iv)), and these fees must be made available solely to pay for the costs of each activity for which the fee was incurred (section 743(b)(3)). These fees are effective on October 1, 2024, and will remain in effect through September 30, 2025. Section 743(b)(2)(B)(iii) of the FD&C Act directs FDA to develop a proposed set of guidelines in consideration of the burden of fee amounts on small businesses. As a first step in developing these guidelines, FDA invited public comment on the potential impact of the fees authorized by section 743 of the FD&C Act on small businesses (76 FR 45818, August 1, 2011). The comment period for this request ended November 30, 2011. As stated in FDA’s October 2011 “Guidance

¹ The term “food” for purposes of this document has the same meaning as such term in section 201(f) of the FD&C Act (21 U.S.C. 321(f)).

for Industry: Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act” (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-implementation-fee-provisions-section-107-fda-food-safety-modernization-act>), because FDA recognizes that for small businesses the full cost recovery of FDA reinspection or recall oversight could impose severe economic hardship, FDA intends to consider reducing certain fees for those firms. FDA does not intend to issue invoices for reinspection or recall order fees until FDA publishes a guidance document outlining the process through which firms may request a reduction in fees.

In addition, as stated in the October 2011 Guidance, FDA is in the process of considering various issues associated with the assessment and collection of importer reinspection fees. The fee rates set forth in this notice will be used to determine any importer reinspection fees assessed in FY 2025.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2025

FDA is required to estimate 100 percent of its costs for each activity in order to establish fee rates for FY 2025. In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all the remaining funds (operating funds) available to FDA are used to support FDA employees by paying for rent, travel, utility, information technology (IT), and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2025

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered “hours worked” for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an Agency-wide total cost per FTE requires three primary cost elements: payroll, nonpayroll, and rent.

We have used an average of past year cost elements to predict the FY 2025 cost. The FY 2025 FDA-wide average cost for payroll (salaries and benefits) is