United States Food and Drug Administration

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

OMB Control No. 0910-0594--EXTENSION

SUPPORTING STATEMENT

Part A: Justification

1. Circumstances Making the Collection of Information Necessary

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 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)). 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*.

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.

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.

We therefore request extension of OMB approval of the information collection provisions found in the special controls guidance discussed in this supporting statement and codified under 21 CFR § 864.9245.

2. Purpose and Use of the Information Collection

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.

The reporting of adverse 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.

In the special control guidance document, FDA recommends that manufacturers include in their three annual reports a summary of adverse reactions maintained by the collecting or transfusing facility or similar reports of adverse events collected.

Description of Respondents: Respondents to this information collection are manufacturers of automated blood cell separator devices.

3. Use of Improved Information Technology and Burden Reduction

The Center for Biologics Evaluation and Research (CBER) currently accepts annual reports 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. FDA is not aware of any other improved technology to reduce the burden. FDA continues to pursue methods of applying technology to reduce the burden to the respondents of its information collection. We estimate that 100% of the respondents will use electronic means to fulfill the agency's requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. In the special control guidance document, FDA recommends that manufacturers include in their three annual reports a summary of adverse events maintained by the collecting or transfusing facility or similar reports of adverse events collected in addition to those required under the MDR regulation. The guidance does not request duplicate MDR reporting in the annual report.

5. Impact on Small Businesses or Other Small Entities

There is no impact on small businesses.

While FDA does not believe it can apply different standards with respect to regulatory and statutory requirements, FDA does provide special help to small businesses. CBER's Office of Communication, Outreach, and Development, Division of Manufacturer's Assistance and Training, provides assistance to small businesses concerning FDA's regulatory requirements. We also provide a Small Business Guide on our website at http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory requirements and applicable regulations.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this information collection.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the *Federal Register* of April 22, 2024 (89 FR 44991). No comments were received.

9. Explanation of Any Payment or Gift to Respondent

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Data will be kept private to the extent allowed by law.

The Privacy Act of 1974

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted may include name, address, telephone number, email address and fax number when annual reports are collected. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate guidance, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

This information collection does not involve questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

We estimate the burden of this information collection as follows:

Table 1.--Estimated Annual Reporting Burden

21 CFR 846; Recommended Activity; Guidance Section	No. of Respondents	No. of Responses per Response	Total Annual Responses	Average Burden per Response	Total Hours
21 CFR 864.9245; Annual Report; Section VI, Special Controls	3	1	3	5	15

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 total annual burden of this collection of information is 15 hours.

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 associated with reporting under 21 CFR 864.9245 are already reported and approved under OMB Control Numbers 0910-0120 (premarket notification submission 510(k), 21 CFR part 807, subpart E), and 0910-0437 (MDR)
(21 CFR Part 803).

12b. Annualized Cost Burden Estimate

The estimated annual cost to respondents is $960.00.

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Reporting	15	$64.00	$960.00

The cost estimate is based on a regulatory affairs specialist, at a pay rate of $64.00/hour, who would be responsible for preparing the submission to FDA. The estimated average hourly pay rate includes benefits but no overhead costs.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers or Capitol Costs

There are no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to Federal Government

The estimated annualized cost to the Federal Government is $249.00. The estimate includes the time it takes FDA to review the additional information requested in the annual report. The estimated cost is based on an average grade scale of a GS-14 ($83/hour) reviewer. The salary estimate includes benefits but no overhead costs.

Activity	Number of Responses	Hours per Response	Cost per Hour	Total Cost
Review	3	1	$ 83.00	$ 249.00

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since 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 estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date in the guidance as required by 5 CFR 1320.8. The OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.