United States Food & Drug Administration

Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle

OMB Control No. 0910-0594

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations. Under the Safe Medical Devices Act of 1990 (Public Law 101 – 629), 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 a device. The special controls guidance document entitled, "*Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle*," 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, as codified under 21 CFR 864.9245.

The guidance provides for annual reporting of 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) (21 CFR Part 803)); any subsequent change to the device requiring the submission of a premarket notification in accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act); and any subsequent change to the preamendments class III device requiring a 30-day notice in accordance with 21 CFR 814.39(f).

For currently marketed products not approved under the premarket approval (PMA) 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 section 510(k) of the FD&C Act (21 U.S.C. 360(k)) clearance. Also, a manufacturer of a device determined to be substantially equivalent to the centrifugal or filtration-based automated blood cell separator device intended for the routine collection of blood and blood components, should comply with the same general and special controls. These special controls along the general controls should provide reasonable assurance of the safety and efficacy of the device.

Accordingly, we are requesting extension of OMB approval for 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

Collecting or transfusing facilities, the intended users of the device, and the device manufacturers have certain responsibilities under the Federal regulations. For example, collecting or transfusing facilities 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 (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 (21 CFR 803.50).

In the special controls guidance document, FDA recommends that manufacturers include certain information in their three annual reports including, but not limited to, a summary of anticipated and unanticipated adverse events that have occurred. 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.

3. Use of Improved Information Technology and Burden Reduction

The Center for Biologics Evaluation and Research (CBER) currently accepts the electronic submissions of certain information. There is no change to the currently available methods of electronic submission of annual reports. We are not aware of any other improved technology to reduce the burden.

4. Efforts to Identify Duplication and Use of Similar Information

In the special controls 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

The information collection does not impose undue burden on small entities. Rather, 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 controls guidance document recommends that manufacturers of these devices file with FDA an annual report for three 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.

FDA must apply the regulatory and statutory requirements equally to all establishments regardless of size, however we do 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.

6. Consequences of Collecting the Information Less Frequently

There are regulatory compliance consequences if the collection of information is not conducted or is conducted less frequently. The frequency of collection of three consecutive years in the annual report is to provide for donor and user safety, and to reveal trends that may identify safety hazards.

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

There are no special circumstances for this collection of information.

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 on February 22, 2018 (83 FR 7745). One comment was received but was not responsive to the four information collection topics solicited and was therefore not addressed by the agency.

9. Explanation of Any Payment or Gift to Respondent

No payment or gifts are provided to respondents to the information collection.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received by FDA is consistent with the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)), and FDA's published regulations of "Public Information" under 21 CFR Part 20 and 21 CFR 807.95 (Confidentiality of Information).

11. Justification for Sensitive Questions

Questions of a sensitive nature are not applicable to this collection of information.

12. Estimates of Annualized Burden Hours and Costs

The total annual estimated burden for this collection of information is 15 hours.

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden					
Activity	No. of Respondents	No. of Responses per Response	Total Annual Responses	Avg. Burden per Response	Total Hours
Annual Report	3	1	3	5	15

Based on FDA records, there are approximately 3 manufacturers of automated blood cell separator devices. The estimated average burden per response is based on the 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 estimated at approximately 15 hours.

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. Annual Cost Burden Estimate

The estimated annual cost to respondents is $840.00.

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Reporting	15	$56.00	$840.00

The cost estimate is based on a regulatory affairs specialist, at a pay rate of $56.00/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/Capitol Costs

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

14. Annualized Cost to Federal Government

The estimated annualized cost to the Federal Government is $210.00. The estimate includes the time by 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 ($70/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	$ 70.00	$ 210.00

15. Explanation for Program Changes or Adjustments

The information collection reflects adjustments. We have decreased our estimated number of respondents from 4 to 3, which resulted in a corresponding adjustment in burden hours from 20 to 15. We attribute the decrease to fewer submissions since last OMB review and approval of the information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

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

FDA is not seeking approval to exempt the display of the expiration date of the OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.