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

0910-0594

SUPPORTING STATEMENT

JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting an extension of Office of Management and Budget (OMB) Control No. 0910-0594 and OMB approval of the information collection provision contained in the above-referenced special control guidance document. The information collection provision is listed below:

Annual Report	Reporting	The annual report should include a summary of adverse reactions maintained by the collecting or transfusing facility or similar reports of adverse events collected in addition to those required under the Medical Device Reporting (MDR) regulation.

Under the Safe Medical Devices Act of 1990 (Public Law 101 – 629, 104 Stat 4511), 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 document serves to support the reclassification from Class III to Class II of the automated blood cell separator device operating on a centrifugal separation principle intended for the routine collection of blood and blood components as well as the special control for the automated blood cell separator device operating on a filtration separation principle intended for the routine collection of blood and blood components reclassified as Class II (21 CFR 864.9245).

For currently marketed products not approved under the premarket approval (PMA) process, the manufacturer should file with FDA for three 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 Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360) clearance. Any subsequent change to the device requiring the submission of a premarket notification in accordance with section 510(k) of the 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 blood cell separator device intended for the routine collection of blood and blood components, should comply with the same general and special controls.

The annual report should include, at a minimum, a summary of anticipated and unanticipated adverse events that have occurred, such as those required under 21 CFR 606. 160(b)(1)(iii) to be recorded and maintained by the facility using the device to collect blood and blood components, and that are not required to be reported by manufacturers under Medical Device Reporting (MDR) (21 CFR part 803). Additional information may need to be reported as well.

2. Purpose and Use of the Information Collection

Collecting or transfusing facilities and manufacturers have certain responsibilities under the Code of Federal Regulations. Among others, collecting or transfusing facilities are required to maintain records of any reports of complaints of adverse reactions (21 CFR 606.170), while the 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 (§ 803.50).

In the special control guidance document, FDA recommends that manufacturers include in their three annual reports a summary of adverse events that have occurred and that are not required to be reported by manufacturers under MDR. Other information may also have to be reported. The MedWatch medical device reporting code instructions (*http://www.fda.gov/cdrh/mdr/373.html*) contains a comprehensive list of adverse events associated with device use, including most of those events that FDA recommends summarizing in the annual report.

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. FDA is not aware of any other improved technology to reduce the burden.

4. Efforts to Identify Duplication and Use of Similar Information

In the guidance document, we recommend 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.

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5. Impact on Small Businesses or Other Small Entities

There is no impact on small businesses, however, reclassification of this device from Class III to Class II for the intended use of routine collection of blood and blood components will relieve manufacturers of the burden of complying with the premarket approval requirements of section 515 of the 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 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.

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 Manufacturers Assistance and Training, provides assistance to small businesses subject to 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 March 2, 2009 (74 FR 9097). No comments on the collection of information were received from the public.

9. Explanation of Any Payment or Gift to Respondent

No payments or gifts were provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received by FDA is consistent with the Freedom of

Information Act (5 U.S.C. 552(b)), and FDA's regulations under 21 CFR Part 20 and 21 CFR 807.95.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

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

Estimated Annual Reporting Burden					
Reporting Activity	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Annual Report	4	1	4	5	20

Based on FDA records, there are approximately four manufacturers of automated blood cell separator devices. We estimate that the manufacturers will spend approximately five hours preparing and submitting the annual report. The total annual burden of this collection of information is estimated at approximately 20 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).

Cost to Respondents

The estimated annual cost to respondents is $840.00.

Activity	No. of Hours	Cost per hour	Total Cost
Reporting	20	$48.00	$960.00

The cost estimate is based on a regulatory affairs specialist, at a pay rate of $48.00/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 Cost Burden to Respondents and Record Keepers

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

14. Annualized Cost to Federal Government

The estimated annualized cost to the Federal Government is $248.00. 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 ($62/hour) reviewer. The salary estimate includes benefits but no overhead costs.

Activity	Number of Responses	Hours per Response	Cost per Hour	Total Cost
Review	4	1	$ 62.00	$ 248.00

15. Explanation for Program Changes or Adjustments

There is no change in burden from the previous submission.

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

N/A