

**Supporting Statement for  
Draft Guidance for Industry and Food and Drug Administration Staff - Class II  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**

**JUSTIFICATION**

1. Need and Legal Basis

The Food and Drug Administration (FDA) is requesting Office of Management and Budget (OMB) approval of the information collection provision contained in the above-referenced special control guidance document (Tab A). 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. Also, equipment failures, including software, hardware, and disposable item failures should be reported.
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Under the Safe Medical Devices Act of 1990 (Pub. L. 101-629, 104 Stat. 4511) (Tab 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 document serves as the special control 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 (see Proposed Rule; March 10, 2005, 70 FR 11887) (Tab C); and serves as the special control for the filtration-based device with the same intended use reclassified as class II on February 28, 2003 (68 FR 9530) (Tab D). The final rule for the automated blood cell separator device operating on a centrifugal separation principle will be published in conjunction with the special controls guidance document.

For currently marketed products not approved under the Premarket Approval (PMA) process (21 CFR Part 814), 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 premarket notification (510(k)) clearance. 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 act) (21 U.S.C. 301) (Tab E) 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 donor adverse device 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 might not be reported by manufacturers under Medical Device Reporting (MDR) (21 CFR Part 803)(OMB No. 0910-0437 expires 5/31/2009). Also, equipment failures, including software, hardware, and disposable item failures should be reported.

## 2. Information Users

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)(2)). In the guidance document, we recommend 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 in addition to those required under the MDR regulation.

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. Improved Information Technology

The Center for Biologics Evaluation and Research 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. Duplication of Similar Information

In the guidance document, we recommend 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 in addition to those required under the MDR regulation. The guidance does not request duplicate MDR reporting.

5. Small Businesses

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) (Tab F), 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. The Center for Biologics Evaluation and Research provides assistance to small businesses subject to FDA's regulatory requirements.

6. Less Frequent Collection

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

There are no special circumstances for this collection of information.

8. Federal Register Notice/Outside Consultation

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the *Federal Register* on March 10, 2005 (70 FR 11990) (Tab G). No comments on the collection of information were received from the public.

9. Payment/Gift to Respondent

No payments or gifts were provided to respondents.

10. Confidentiality

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. Sensitive Questions

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

12. Burden Estimate (Total Hours and Wages)

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 an estimated 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 proposed 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). Currently, manufacturers of medical devices are required to submit to FDA individual adverse event reports of death, serious injury, and malfunctions (21 CFR §§ 803.50 and 803.53). The manufacturer is responsible for conducting an investigation of each event and evaluating the cause of the event (21 CFR 803.50(b)(2)).

The reporting recommended in the special control guidance document broadens the information to be reported by manufacturers to FDA. We are recommending that the manufacturer submit annually, for three consecutive years, a summary of all adverse events, including those reported under 21 CFR Part 803. The Mandatory MedWatch Reporting Form 3500A: Codes Manual contains a comprehensive list of adverse events associated with device use, including most of those events that we recommend summarizing in the annual report.

Cost to Respondents

The estimated annual cost to respondents is \$840.00.

Activity	No. of Hours	Cost per hour	Total Cost
Reporting	20	\$42.00	\$840.00

The cost estimate is based on a regulatory affairs specialist, at a pay rate of \$42.00/hour, who would be responsible for preparing the submission to FDA. The estimated average hourly pay rate includes benefits but no overhead costs.

13. Capital Costs (Maintenance of Capital Costs)

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

14. Cost to Federal Government

The estimated annualized cost to the Federal Government is \$54.00. 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 (\$54/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	\$ 54.00	\$ 54.00

15. Program or Burden Changes

Changes in burden are not applicable since this is a new collection of information.

16. Publication and Tabulation Dates

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

17. Display of OMB Approval Date

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 Section 19 of Form OMB 83-I.