the Orange Book. In addition, for patents issued after the date of approval of an application, Form FDA 3542 must be submitted within 30 days of the date of issuance of the patent.

Following publication of the June 2003 final rule, the numbers of patents submitted to FDA for listing in the Orange Book in 2004 and 2005 were 244 and 295, respectively, for an annual average of 269.5 ((244 patents + 295 patents) / 2 years = 269.5 patents / year). Because many of these individual patents are included in multiple NDA submissions, there could be multiple declarations for a single patent. From our review of submissions, we believe that approximately 14 percent of the patents submitted are included in multiple NDA submissions, and thus require multiple patent declarations. Therefore, we estimate that 38 (269.5 patents x 14 percent) patent declarations will be multiple listings, and there will be 308 (269.5 declarations + 38 declarations = 307.5 declarations) total annual patent declarations on Form FDA 3542.

As we approved 113 and 78 NDAs in 2004 and 2005, respectively, we assume there will be 96 ((113 approvals + 78 approvals) / 2 years = 95.5 approvals / year) instances where an NDA holder would be affected by the patent declaration requirements, and that each of these NDA holders would, on average, submit 3.2 (308 declarations / 96 instances = 3.2 declarations per instance) declarations on Form FDA 3542.

As we received 112 and 115 NDAs in 2004 and 2005, respectively, we assume there will be 114 ((112 applications + 115 applications) / 2 years = 113.5 applications / year) instances where an NDA holder would be affected by the patent declaration requirements. We estimate, based on a proportional increase from the number of declarations for approved NDAs, that there will be an annual total of 365 (114 instances x 3.2 declarations per instance = 365 declarations) declarations on Form FDA 3542a submitted with these applications.

The previous burden hour estimate of 1,684 hours for § 314.50 covered paragraphs (a) through (f), (k), and (h) (citing § 314.53) and FDA Forms 3542 and 3542a (see June 2003 final rule), due to the difficulty in determining what proportion of the burden hour estimate for § 314.50(a) through (f), (h), and (k), was attributable to patent declarations. Based upon information provided by regulated entities and other information, we estimate that the information collection burden associated with § 314.50(h) (citing § 314.53) and FDA Forms 3542a and 3542 will be approximately 20 hours and 5 hours per response, respectively.

Thus, the information collection burden for § 314.50(h) (citing § 314.53) and FDA Forms 3542 and 3542a will decrease from the estimate we made in the June 2003 final rule for § 314.50(a) through (f), (h), and (k), and FDA Forms 3542 and 3542a of 498,464 hours to 8,840 hours ((365 annual responses x 20 hours per response = 7,300 hours) + (308 annual responses x 5 hours per response = 1,540 hours) = 8,840 total hours).

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Form FDA 3542a	114	3.2	365	20	7,300
Form FDA 3542	96	3.2	308	5	1,540
Total					8,840

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

Dated: May 25, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–8570 Filed 6–1–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0019]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry and Food and Drug Administration Staff on Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation 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: Fax written comments on the collection of information by July 3, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Draft Guidance for Industry and FDA Staff on Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle

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. This draft 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 of March 10, 2005, 70 FR 11887), and serves as the special control for the filtration-based device with the same intended use reclassified as class II in the **Federal Register** of February 28, 2003 (68 FR 9530). 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, 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) 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. 360(k)) 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 § 606.160(b)(1)(iii) (21 CFR 606.160(b)(1)(iii))[1] 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). Also, equipment failures, including software, hardware, and disposable item failures' should be reported. 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.

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 PMA 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 3 consecutive years, this would be less burdensome than the current postapproval requirements under part 814, subpart E (21 CFR part 814, subpart E), including the submission of periodic reports under § 814.84.

Collecting or transfusing facilities and manufacturers have certain responsibilities under the CFR. Among others, collecting or transfusing facilities are required to maintain records of any reports of complaints of adverse reactions (§ 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 under part 803 (21 CFR part 803), specifically in § 803.50(b)(2). In the draft 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.

In the **Federal Register** of March 10, 2005 (70 FR 11990), FDA published a 60-day notice requesting public comment on the information collection provisions. One public comment was received but it did not relate to the collection of information.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
Annual Report	4	1	4	5	20

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

Based on FDA records, there are an estimated four 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 estimated at approximately 20 hours.

Other burden hours associated with proposed 21 CFR 864.9245 are already reported and approved under OMB control number 0910–0120 (premarket notification submission in accordance with section 510(k) of the act, and 21 CFR part 807, subpart E), and OMB control number 0910–0437 (MDR). Currently, manufacturers of medical devices are required to submit to FDA individual adverse event reports of death, serious injury, and malfunctions (§§ 803.50 and 803.53). The manufacturer is responsible for conducting an investigation of each event and evaluating the cause of the event (§ 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 3 consecutive years, a summary of all adverse events, including those reported under part 803. 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 we recommend summarizing in the annual report.

Dated: May 25, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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[1]Section 606.160(b)—''Records shall be maintained that include, but are not limited to, the following when applicable: * * * (1)(iii) Donor adverse reaction complaints and reports, including results of all investigations and followup.''