Written comments and recommendations concerning the proposed information collection should be sent by August 31, 2009 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–6974.

Dated: July 27, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–18313 Filed 7–30–09; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0092]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 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

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 August 31, 2009.

ADDRESSES: 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, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0594. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

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.

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 Number 0910–0594)—Extension

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 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 (§ 864.9245 (21 CFR 864.9245)).

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 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 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 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.

Reclassification of this device from class III to class II for the intended use of routine collection of blood and blood components relieves 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 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 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 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 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)). 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. 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.

In the **Federal Register** of March 2, 2009 (74 FR 9097), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Reporting Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	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 approximately four manufactures of automated blood cell separator devices. We estimate that the manufacturers will spend approximately 5 hours preparing and submitting the annual report.

Other burden hours required for § 864.9245 are reported and approved under OMB control number 0910–0120 (premarket notification submission 501(k), 21 CFR part 807, subpart E), and OMB control number 0910–0437 (MDR).

Dated: July 24, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–18354 Filed 7–30–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: National Evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program: Phase VI–NEW

The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Mental Health Services is responsible for the national evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program (Children's Mental Health Initiative—CMHI) that will collect data on child mental health outcomes, family life, and service system development and performance. Data will be collected on 26 service systems, and approximately 5,541 children and families.

Data collection for this evaluation will be conducted over a five-year period. Child and family outcomes of interest will be collected at intake and during subsequent follow-up sessions at six-month intervals. The length of time that individual families will participate in the study ranges from 12 to 24 months depending upon when they enter the evaluation. The outcome measures include the following: Child symptomatology and functioning, family functioning, satisfaction, and caregiver strain. The core of service system data will be collected every 18–24 months throughout the 5-year evaluation period, with a sustainability survey conducted in years 3 and 5. Service utilization and cost data will be tracked and submitted to the national evaluation every six months using two tools, the Flex Fund Tool and the Services and Costs Data Tool, to estimate average cost of treatment per child, distribution of costs, and allocation of costs across service categories. Service delivery and system variables of interest include the following: Maturity of system of care development in funded system of care communities, adherence to the system of care program model, and client service experience. We will also conduct a comprehensive evaluation of the CMHI's data driven technical assistance; this component of the evaluation will employ a mixed-methods approach, combining qualitative and quantitative data to provide a comprehensive assessment of the continuous quality improvement (CQI) process in funded system of care communities. Specifically, data will be gathered through three complementary activities: A baseline survey of key constituents in all funded communities; a subsequent monitoring survey administered every two years to the same constituents; and biennial case studies of four selected communities.

In addition, the evaluation will include three special studies: (1) The sector specific assessment and quasi-experimental comparison study will examine in more detail the outcomes and service experience of children from multiple child-serving sectors and, through child-level matching, compare these outcomes with those not receiving system of care services; (2) The Alumni Network Study will examine the effectiveness of the system of care Alumni Network Web site by evaluating end-user satisfaction and usability of the Web site and will also assess the collaboration between communities via a Web-based Networking and Collaboration Survey that will measure the nature and extent of the interaction between communities; (3) The Study of State Strategies for Sustainability will examine the state's role in sustaining communities after federal funding ceases and describe effective strategies for sustaining funded systems of care. A short version of the sustainability survey developed for this evaluation will be used to gather this information.

Internet-based technology such as Web-based surveys and data entry and management tools will be used in this evaluation. The measures of the national evaluation address the national outcome measures for mental health programs as currently established by SAMHSA.

The average annual respondent burden is estimated below. The estimate reflects the average number of respondents in each respondent category, the average number of responses per respondent per year, the average length of time it will take to complete each response, and the total average annual burden for each category of respondent, and for all categories of respondents combined.