of the public the opportunity to provide comments to the Board. Public participation and ability to comment will be limited to time and space available. Public comment will be limited to no more than 3 minutes per speaker. To be placed on the public participant list, you should notify the operator when you enter the call-in number.

Any members of the public who wish to have printed material distributed to the NBSB should submit materials via email at *NBSB@HHS.GOV,* with ''NBSB Public Comment'' as the subject line, prior to the close of business one week before each meeting (conference call). A draft agenda and any additional materials/agendas will be posted on the NBSB Web site (*HTTP://WWW.HHS.GOV/ASPR/OMSPH/NBSB/*) prior to the meeting.

Dated: July 24, 2009.

Nicole Lurie,

Assistant Secretary for Preparedness and Response, Rear Admiral, U.S. Public Health Service.

[FR Doc. E9–18372 Filed 7–30–09; 8:45 am]

BILLING CODE 4150–37–P

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: Drug and Alcohol Services Information System (DASIS)—(OMB No. 0930–0106)—Revision

The DASIS consists of three related data systems: the Inventory of Substance Abuse Treatment Services (I–SATS); the National Survey of Substance Abuse Treatment Services (N–SSATS), and the Treatment Episode Data Set (TEDS). The I–SATS includes all substance abuse treatment facilities known to SAMHSA. The N–SSATS is an annual survey of all substance abuse treatment facilities listed in the I–SATS. The TEDS is a compilation of client-level admission data and discharge data submitted by States on clients treated in facilities that receive State funds. Together, the three DASIS components provide information on the location, scope and characteristics of all known drug and alcohol treatment facilities in the United States, the number of persons in treatment, and the characteristics of clients receiving services at publicly funded facilities. This information is needed to assess the nature and extent of these resources, to identify gaps in services, to provide a database for treatment referrals, and to assess demographic and substance-related trends in treatment. In addition, several National Outcome Measures (NOMS) data elements are collected in TEDS to assess the performance of the Substance Abuse Prevention and Treatment (SAPT) Block Grant.

The request for OMB approval will include a request to conduct the 2010 through 2012 N–SSATS and Mini-N–SSATS. The Mini-N–SSATS is a procedure for collecting services data from newly identified facilities between main cycles of the survey and will be used to improve the listing of treatment facilities in the on-line treatment facility Locator. The N–SSATS questionnaire is expected to remain unchanged except for minor modifications to wording. If there is a need for substantial revision to the N–SSATS questionnaire during the period of this clearance, a supplemental request for clearance will be submitted.

The OMB request will also include the collection of TEDS data, including the addition of two new NOMS data elements to the TEDS client-level record. To the extent that states already collect the elements from their treatment providers, the following elements will be included in the TEDS data collection: Frequency of attendance at self-help programs in past 30 days at admission; and frequency of attendance at self-help programs in past 30 days at discharge. No significant changes are expected in the other DASIS activities.

Estimated annual burden for the DASIS activities is shown below:

Type of respondent and activity	Number of respondents	Responses per respondent	Hours per response	Total burden hours
States:				
TEDS Admission Data	52	4	6.25	1,300
TEDS Discharge Data	52	4	8.25	1,716
TEDS Discharge Crosswalks	5	1	10	50
I–SATS Update [1]	56	70	.08	314
State Subtotal	56			3,380
Facilities:				
I–SATS Update [2]	200	1	.08	16
N–SSATS questionnaire	17,000	1	.67	11,390
Augmentation screener	1,000	1	.08	80
Mini N–SSATS	2,000	1	.42	840
Facility Subtotal	20,200			12,326
Total	20,256			15,706

[1] States forward to SAMHSA information on newly licensed/approved facilities and on changes in facility name, address, status, etc. This is submitted electronically by nearly all States.

[2] Facilities forward to SAMHSA information on new facilities and on changes to existing facilities. This is submitted by e-mail by nearly all facilities.

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: