Agendas after considering comments on the drafts. For more information, see the link above and choose ''Sector-based Approach,'' ''NORA Sector Councils,'' ''Sector Agendas'' and ''Comment on Draft Sector Agendas'' from the right-side menu.

Contact Person for Technical Information: Sidney C. Soderholm, PhD, NORA Coordinator, e-mail *noracoordinator@cdc.gov,* telephone (202) 245–0665.

Dated: February 18, 2009.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–4318 Filed 2–27–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0092]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information concerning class II special controls for automated blood cell separator device operating by centrifugal or filtration separation principle.

DATES: Submit written or electronic comments on the collection of information by May 1, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 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 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.

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: February 20, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–4315 Filed 2–27–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Part C Early Intervention Services Grant

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of non-competitive program expansion supplemental award.

SUMMARY: The Health Resources and Services Administration (HRSA) will be providing temporary critical HIV medical care and treatment services through the Greenwood Leflore Hospital (GLH) Magnolia Medical Clinic to avoid a disruption of HIV clinical care to clients in Bolivar, Sunflower and Washington Counties in Mississippi.

SUPPLEMENTARY INFORMATION: Intended recipient of the award: GLH Magnolia Medical Clinic, Greenwood, Mississippi.

Amount of the Award: $73,125 to ensure ongoing clinical services to the target population.

Authority: Section 2651 of the Public Health Service Act, 42 U.S.C. 300ff–51.

CFDA Number: 93.918.

Period of Support: The period of supplemental support is from April 1, 2009 to June 30, 2009.

Justification for the Exception to Competition:

Critical funding for HIV medical care and treatment services to clients in Bolivar, Sunflower and Washington Counties in Mississippi will be continued through a non-competitive program expansion supplement to an existing grant award to the GLH Magnolia Medical Clinic in Greenwood, Mississippi. This is a temporary award because the previous grant recipient serving this population notified HRSA that it would not continue in the program. GLH Magnolia Medical clinic is the best qualified grantee for this supplement since it serves many of the former grantee's patients and is the closest Part C Ryan White HIV/AIDS Program to the former grantee. Further funding beyond June 30, 2009 for this service area will be competitively awarded during the next Part C HIV Early Intervention Service competing application process for FY 2009.

FOR FURTHER INFORMATION CONTACT: Kathleen Treat, via email *ktreat@hrsa.gov*, or via telephone, 301–443–0493.

Dated: February 22, 2009.

Elizabeth M. Duke,

Administrator.

[FR Doc. E9–4277 Filed 2–27–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2008–0333]

Delaware River and Bay Oil Spill Advisory Committee; Meeting

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The Delaware River and Bay Oil Spill Advisory Committee (DRBOSAC) will meet in Philadelphia, PA to discuss various issues to improve oil spill prevention and response strategies for the Delaware River and Bay. This meeting will be open to the public.

DATES: The Committee will meet on Wednesday, March 18, 2009, from 10 a.m. to 1 p.m. Written material and requests to make oral presentations should reach the Coast Guard on or before March 11, 2009. Requests to have a copy of your material distributed to each member of the committee should reach the Coast Guard on or before March 11, 2009.

ADDRESSES: The Committee will meet at Coast Guard Sector Delaware Bay, 1 Washington Ave., Philadelphia, PA 19147. Send written material and requests to make oral presentations to Gerald Conrad, liaison to the Designated Federal Officer (DFO) of the DRBOSAC, at the address above. This notice and