

management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: February 3, 2009.

Elaine L. Baker,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Injury Prevention and Control Initial Review Group (NCIPC, IRG)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Time and Date: 9 a.m.-9:30 a.m., March 19, 2009 (Open). 9:30 a.m.-6 p.m., March 19, 2009 (Closed).

Place: Embassy Suites of Buckhead, 3285 Peachtree Road, Atlanta, GA 30305, telephone: (404) 261-7733.

Status: Portions of the meetings will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92-463.

Purpose: This group is charged with providing advice and guidance to the Secretary, Department of Health and Human Services, and the Director, CDC, concerning the scientific and technical merit of grant and cooperative agreement applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct specific injury research that focuses on prevention and control.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of individual research grant applications submitted in response to Fiscal Year 2009 Requests for Applications related to the following individual research announcement: RFA-CE-09-005, "Research Priorities in Acute Injury Care (R01)".

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Jane Suen, Dr.P.H., M.S., NCIPC, CDC, 4770 Buford Highway, NE., Mailstop F-62, Atlanta, Georgia 30341, telephone: (770) 488-4281; fax (770) 488-4422.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and

other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: February 19, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Public Meeting

AGENCY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public meeting.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following public meeting: "Partnerships to Advance the National Occupational Research Agenda (NORA)."

Public Meeting Time and Date: 10 a.m.-4 p.m. EDT, June 17, 2009.

Place: Patriots Plaza, 395 E Street, SW., Conference Room 9000, Washington, DC 20201.

Purpose of Meeting: The National Occupational Research Agenda (NORA) has been structured to engage partners with each other and/or with NIOSH to advance NORA priorities. The NORA Liaison Committee continues to be an opportunity for representatives from organizations with national scope to learn about NORA progress and to suggest possible partnerships based on their organization's mission and contacts. This opportunity is now structured as a public meeting via the internet to attract participation by a larger number of organizations and to further enhance the success of NORA. Some of the types of organizations of national scope that are especially encouraged to participate are employers, unions, trade associations, labor associations, professional associations, and foundations. Others are welcome.

This meeting will include updates from NIOSH leadership on NORA as well as updates from approximately half of the Sector Councils on their progress, priorities, and implementation plans to date, including the Construction Sector; Manufacturing Sector; Services Sector;

Public Safety Sub-Sector; and Wholesale and Retail Trade Sector. Updates will also be given on cross-council coordination activities in the areas of surveillance and safety culture. After each update, there will be time to discuss partnership opportunities.

Status: The meeting is open to the public, limited only by the capacities of the conference call and conference room facilities. There is limited space available in the meeting room (capacity 34). Therefore, information to allow participation in the meeting through the internet (to see the slides) and a teleconference call (capacity 50) will be provided to registered participants. Participants are encouraged to consider attending by this method. Each participant is requested to register for the free meeting by sending an e-mail to noracoordinator@cdc.gov containing the participant's name, organization name, contact telephone number on the day of the meeting, and preference for participation by web meeting (requirements include: computer, internet connection, and telephone, preferably with "mute" capability) or in person. An e-mail confirming registration will include the details needed to participate in the web meeting. Non-US citizens are encouraged to participate in the web meeting. Non-US citizens registering to attend in person after June 3 will not have time to comply with security procedures.

Background: NORA is a partnership program to stimulate innovative research in occupational safety and health leading to improved workplace practices. Unveiled in 1996, NORA has become a research framework for the nation. Diverse parties collaborate to identify the most critical issues in workplace safety and health. Partners then work together to develop goals and objectives for addressing those needs and to move the research results into practice. The NIOSH role is facilitator of the process. For more information about NORA, see <http://www.cdc.gov/niosh/nora/about.html>.

Since 2006, NORA has been structured according to industrial sectors. Eight sector groups have been defined using the North American Industrial Classification System (NAICS). After receiving public input through the web and town hall meetings, NORA Sector Councils have been working to define sector-specific strategic plans for conducting research and moving the results into widespread practice. During 2008-09, most of these Councils have posted draft strategic plans for public comment. Two have posted finalized National Sector

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.

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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