

promotion programs; administering a national occupational safety and health program; controlling the introduction and spread of infectious diseases; and providing consultation and assistance to other nations and international agencies to assist in improving their disease prevention and control, environmental health, and health promotion activities. CDC carries out these functions through a number of Coordinating Centers/Offices and National Centers and Institutes with expertise and responsibilities in specific areas.

**Matters to be Discussed:** The agenda will include discussions on program activities, including scientific programs, that will assist in consolidating and refining NCHM vision, mission, goals, organizational structure and expanding and implementing its science for the National Center for Health Marketing; and discussions related to the National Center's role in preparedness, response and recovery with regards to an outbreak of pandemic influenza

Agenda items are tentative and subject to change.

**Contact Person for More Information:** Dionne R. Mason, Committee Management Specialist, NCHM, 1600 Clifton Road, Mail Stop E-21, Atlanta, Georgia 30333, Telephone: (404) 498-2314, Fax (404) 498-2221. The deadline for notification of attendance is November 20, 2008.

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: November 4, 2008.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention (CDC)

#### 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), CDC announces the following meeting for the aforementioned committee:

**Times and Date:** 1 p.m.-2:30 p.m., December 8, 2008 (Closed).

**Place:** Teleconference.

**Status:** The meeting 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 reporting and voting of the peer reviews conducted in response to Fiscal Year 2008 Requests for Applications related to the following individual research announcements: (1) RFA-CD-08-001, "Elimination of Health Disparities Through Translation Research (R18)" and (2) RFA-CE-09-001, "Grants for the Injury Control Research Centers". Agenda items are subject to change as priorities dictate.

**Contact Person for More Information:** Rick Waxweiler, PhD, Director, Extramural Research Program Office, NCIPC and Executive Secretary, NCIPC IRG, CDC, 4770 Buford Highway, NE., Mail Stop F-62, Atlanta, Georgia 30341, Telephone: (770) 488-4850.

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: November 4, 2008.

**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

### Food and Drug Administration

[Docket No. FDA-2008-N-0345]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donor Testing, Donor Notification, and "Lookback"

**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 December 12, 2008.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0116. 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.

#### Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donor Testing, Donor Notification, and "Lookback" (OMB Control Number 0910-0116—Extension)

All blood and blood components introduced or delivered for introduction into interstate commerce are subject to section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262). Section 351(a) requires that manufacturers of biological products, which include blood and blood components intended for further manufacture into injectable products, have a license, issued upon a demonstration that the product is safe, pure and potent and that the manufacturing establishment meets all applicable standards, including those prescribed in the FDA regulations designed to ensure the continued safety, purity, and potency of the product. In addition, under section 361 of the PHS Act (42 U.S.C. 264), by delegation from the Secretary of Health and Human Services, FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

Section 351(j) of the PHS Act states that the Federal Food, Drug, and Cosmetic (FD&C) Act also applies to biological products. Blood and blood components for transfusion or for further manufacture into injectable products are drugs, as that term is