

Dated: April 10, 2007.

**Elaine L. Baker,**

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

[FR Doc. E7-7331 Filed 4-13-07; 10:39 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel "Health Promotion and Disease Prevention Research Centers: Special Interest Project Competitive Supplements (Panel 7)," Request for Application Number (RFA) DP07-002

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 a meeting of the aforementioned Special Emphasis Panel.

*Time and Date:* 12 p.m.-4 p.m., June 5, 2007 (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 Public Law 92-463.

*Matters To Be Discussed:* The meeting will include the review, discussion, and evaluation of research grant applications received in response to RFA DP07-002, "Health Promotion and Disease Prevention Research Centers: Special Interest Project Competitive Supplements (Panel 7)."

*Contact Person for More Information:* Sheree Marshall Williams, PhD, M.Sc., Scientific Review Administrator, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS D72, Atlanta, GA 30333, telephone 404.639.4896.

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: April 10, 2007.

**Elaine L. Baker**

*Acting 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 meetings of the aforementioned committee:

*Times and Dates:*

2 p.m.-5 p.m., May 14, 2007 (Closed).

2 p.m.-5 p.m., May 15, 2007 (Closed).

2 p.m.-5 p.m., May 16, 2007 (Closed).

2 p.m.-5 p.m., May 17, 2007 (Closed).

2 p.m.-5 p.m., May 18, 2007 (Closed).

*Place:* The conference calls will originate at the Centers for Disease Control and Prevention, Vanderbilt Building, Koger Center, Atlanta, Georgia.

*Times and Dates:*

9 a.m.-10 a.m., May 21, 2007 (Open).

10 a.m.-5 p.m., May 21, 2007 (Closed).

9 a.m.-3 p.m., May 22, 2007 (Closed).

3 p.m.-5 p.m., May 22, 2007 (Open).

5 p.m.-7 p.m., May 22, 2007 (Closed).

9 a.m.-5:30 p.m., May 23, 2007 (Closed).

9 a.m.-5 p.m., May 24, 2007 (Closed).

*Place:* Sheraton Midtown Atlanta Hotel Colony Square, Atlanta, Georgia.

*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 and cooperative agreement applications submitted in response to two Fiscal Year 2007 Requests for Applications related to the following individual research announcements: 07002, Family and Dyadic Focused Interventions to

Prevent Intimate Partner Violence; 07003, Maximizing Protective Factors for Youth Violence; 07004, Abusive Head Trauma (AHT) Prevention; 07005, Understanding Bullying and Sexual Violence Perpetration and Factors Associated with Both Outcomes; 07006, Grants for Traumatic Injury Biomechanics Research; 07007, Dissemination Research on Fall Prevention: "Stepping On" in a U.S. Community Setting; and 07008, The Impact of Traumatic Brain Injury Among Incarcerated Persons.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Jane Suen, PhD, NCIPC/IRG, CDC, 4770 Buford Highway, NE., M/S K02, Atlanta, Georgia 30341-3724, telephone 770/488-1240.

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: April 10, 2007.

**Elaine L. Baker,**

*Acting 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

#### Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 72 FR 14578, dated March 28, 2007) is amended to reflect the reorganization of the Coordinating Center for Infectious Diseases, Centers for Disease Control and Prevention.

Section C-B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the mission statements for the *Coordinating Center for Infectious Diseases (CV)* and the *Office of the Director (CVA)*, and insert the following:

*Coordinating Center for Infectious Diseases (CV).* The mission of the Coordinating Center for Infectious Diseases (CCID) is to protect health and enhance the potential for full, satisfying, and productive living across the lifespan of all people in all communities related to infectious diseases. To carry out its mission, CCID: (1) Fosters collaborations across CID's centers, divisions and branches, builds external and internal partnerships, supports both science and program integration, and leverages both human and budgetary resources to increase the Centers for Disease Control and Prevention's (CDC) health impact and achieve population health goals; (2) helps investigate and diagnose infectious diseases of public health significance; (3) coordinates applied and operational research to define, prevent, and control infectious diseases; (4) assists in providing consultation and training to help state and local health departments plan, develop, implement, and improve immunization programs; (5) coordinates research and operational programs to prevent and control vaccine preventable diseases; and (6) assists in providing technical assistance to states, localities, and other nations to investigate and diagnose sexually transmitted diseases (STDs), viral hepatitis, tuberculosis (TB), human immunodeficiency virus (HIV) infections, and retroviruses; and coordinates applied and operational research on the spread, diagnosis, prevention, and control of HIV, other STDs, viral hepatitis, TB, and non-TB mycobacteria, and non-HIV retroviruses.

*Office of the Director (CVS).* (1) Manages, coordinates, and evaluates the activities of the CCID; (2) communicates overarching goals and objectives, and provides leadership, scientific oversight, and guidance in program planning and development; (3) coordinates assistance provided by CCID to other CDC components, other federal, state, and local agencies, the private sector, and other nations; (4) provides and coordinates resource management support services for CCID; (5) manages and coordinates workforce development and succession planning activities within CCID in collaboration with internal and external partners, and coordinates the recruitment, assignment, technical supervision, and career development of staff with emphasis on developing and supporting diversity initiatives and equal opportunity goals; (6) assists in communication activities; (7) fosters collaboration of cross-cutting CCID scientific and programmatic issues through the Strategic Science and

Program Unit; and (8) ensures consistent, efficient, and effective administration of mission support functions through the establishment and management of the Strategic Business Unit.

*Strategic Business Unit (CVA2).* The mission of the Strategic Business Unit (SBU) is to support CCID programs and staff through the efficient, professional, and timely delivery of critical public health mission-support services. In carrying out its mission, the SBU performs the following functions: (1) Provides direct and daily management and execution of domestic travel processing for federal employees, Commissioned Corps, and all CDC-invited guests; (2) provides direct and daily management and execution of the administrative aspects of human resources across CCID, including training and administration of policies and guidelines developed by the Atlanta Human Resources Center, Department of Health and Human Services (HHS), Ethics Office, Financial Management Office (FMO), Office of Commissioned Corps Personnel, Coordinating Office for Global Health (COGH), Office of Personnel Management, Office of Workforce and Career Development, and Procurement and Grants Office (PGO); (3) provides direct and daily management and execution of the coordination of laboratory and office facilities, and supplies technical guidance and expertise regarding occupancy and facilities management to emergency situations, CDC; (4) provides direct and daily management and execution of the distribution, accountability, and maintenance of CDC property and equipment; (5) provides direct and daily management and execution of the creation, organization, access, maintenance, and disposition of CCID records, and of the establishment of policies and procedures coordinating a CCID response to Freedom of Information Act (FOIA) requests; and (6) provides direct and daily management and execution of the coordination of logistics for CCID's federal government committee meetings and conferences.

*Travel (CVA22).* (1) Prepares for approval travel requests, travel orders, vouchers for reimbursement, in-kind, reimbursable, relocation services, and permissive travel documentation for domestic travel; (2) administers and provides oversight for travel cards; follows up with audits; communicates with national centers (NC) regarding possible fraud, delinquencies, and abuses; troubleshoots for lost or stolen cards; and, generates related reports; (3) provides emergency travel support in response to emergencies, outbreaks, and

domestic incidents; (4) prepares group travel memos to HHS for meetings in excess of 20 attendees (meetings), conferences in excess of 99 attendees, actual expense memos, premium class (medical) memos, and cash purchase memos; and (5) provides guidance and expertise pertaining to travel.

*Personnel/Training (CVA23).* (1) Processes security clearance forms, ID badges, and card keys for FTEs and non-FTEs; (2) performs administrative aspects of recruitment, retention and promotion; (3) manages administrative functions related to employee performance (EPMS, ceremonies, awards, promotions); (4) manages administrative functions related to Commissioned Corps; (5) serves as point of contact for payroll issues including time/attendance records, executive pay appointments, bonuses/allowances, and other special pay agreements; (6) manages administrative functions for non-CDC employees including ORISE fellows, Student Temporary Employment Program, contractors, guest researchers, and interagency agreements (IAA); (7) performs administrative functions related to staffing and other human resource issues including employee relations, FTE tracking, on-board strength reports, PeopleSoft Access, WIZ data and staffing lists, individual development plans (IDP), and individual learning accounts (ILA); manages IDP/ILA accounts and tracks completion of IDPs; (8) enters training requests into mainframe and forwards requests to appropriate channels for approval; (9) verifies requested training is on IDP; (10) tracks scheduling and completion of CDC-required training courses; (11) maintains accurate training log in mainframe; (12) tracks and prints certifications for staff that have completed training courses; (13) manages vendor registration process and initiates payment process for vendors who provide training; and (14) assists with scheduling CCID employees for Corporate University courses.

*Procurement/Property/Facilities (CVA24).* (1) Processes purchase orders, requisitions, and contracts using ICE; (2) processes credit card transactions for purchases <\$2,500 using MACCS; (3) manages receiving and acceptance for both ICE and Visa orders; (4) serves as liaison with CCID lead to respond to ICE inquiries; (5) performs administrative tasks related to initiating, processing, and maintaining IAA; (6) processes contract invoices and payments; (7) reviews and approves all issues and requests related to office and laboratory space; (8) serves as liaison with programs and other necessary parties (Buildings and Facilities Office, Office

of Health and Safety (OHS), Office of Security and Emergency Response (OSEP), Real Properties Office, etc.) to oversee the implementation of all approved requests; (9) coordinates funding for facilities projects; (10) works closely with OSEP and Physical Security to coordinate, approve, and monitor access to restricted high security laboratory buildings and select agent laboratories; (11) serves as liaison with architects and engineers regarding construction projects; (12) provides scientific and technical guidance, and coordination of resources during emergency operations; (13) serves on CDC Emergency Response Team subcommittee; (14) accounts for CDC property (computers, laptops, cell phones, Blackberries, etc.) and laboratory equipment; (15) tracks repairs, losses, and maintenance agreements; (16) facilitates acquisition replacement parts; (17) serves as liaison to the Information Technology Services Office for technical approval of information technology (IT) related purchases; (18) coordinates with appropriate parties to access and distribute property and equipment; (19) coordinates annual inventory process; and (20) purchases, maintains, and checks-out/-in barcode scanners for use by programs for annual inventory.

*Records Management/FOIA/Committee/Management/Conference Logistics (CVA25).* (1) Responsible for physical transfer of files to Federal Records Center (pack boxes, record contents, transfer boxes to courier); (2) organizes and classifies files throughout the organization; (3) maintains and staffs file stations throughout the organization; (4) assists the CDC Records Officer in the development of records management schedules; (5) receives and interprets requests directly from CDC FOIA office; (6) checks for similar and/or duplicate requests; (7) performs preliminary work (scanning, copying); (8) creates and maintains files in the FOIA log; (9) disburses requests to center/division/programs (CDP); (10) sends time-sensitive reminders to CDP liaisons and others working on request; (11) receives completed responses from programs; (12) evaluates information and works with the CDC FOIA Office and program coordinators to ensure that all response packages are complete and within the scope of the request; (13) performs secondary review for identifying possibly exempt material; (14) serves as liaison with CDC FOIA Office and CDC Office of General Counsel for complex requests; (15) sends all responses to CDC FOIA Office for final review; (16) works with records

management group to develop and adhere to a uniform record retention policy regarding FOIA requests; (17) conducts training for scientists and program staff on FOIA exemptions and response process; (18) initiates all personnel actions for CCID committee members; (19) coordinates meeting logistics, travel arrangements, production and distribution of materials, and preparation and distribution of meeting transcripts; (20) maintains agendas, minutes, records, reports and transcripts; (21) records action items and provides feedback to the committees via written and electronic correspondence; (22) prepares standardized committee reports for Government Services Agency, HHS, and the Management Analysis and Services Office (MASO); (23) finalizes nominee packages for CCID committees; (24) coordinates contractor support; (25) prepares and assembles technical proposal packages; (26) coordinates administrative requirements to ensure abstract review/approval by appropriate program and scientific staff; (27) processes conference facility and support contracts; (28) finalizes memorandums of understanding, obtain legal clearance as needed, and maintains records; (29) supports conference registration procedures as needed; (30) coordinates communications to committee members, speakers, and attendees as directed by programmatic personnel; (31) processes orders and payments of print and non-print conference materials; (32) assembles conference materials; (33) coordinates follow-up with invited participants; (34) coordinates ordering and shipment of conference supplies to be used on-site; and (35) coordinates on-site conference administrative staffing support.

*Strategic Science and Program Unit (CVA3).* The mission of the Strategic Science and Program Unit (SSPU) is to provide scientific and laboratory services to stakeholders across CCID. In carrying out its mission, the SSPU: (1) Ensures process consistency for science and laboratory related functions across the NCs; (2) facilitates cross-center decision-making regarding science and laboratory activities; (3) facilitates communication regarding scientific and programmatic services across CCID; (4) develops and administers, in collaboration with CCID's divisions/programs/offices, requests for applications and program announcements for extramural research; (5) serves as the focal point for implementing policies and guidelines for the conduct of the peer review of

extramural research grant proposals and subsequent grant administration; (6) monitors the performance of funded extramural research projects in the areas of infectious diseases and immunization; (7) conducts necessary regulatory and ethical reviews for activities involving human participants, including determining whether an activity includes research, includes human subjects, is exempt or requires Institutional Review Board (IRB) approval, and whether an exception is needed to the Public Health Service (PHS) HIV policy; (8) reviews funded activities for application of human research regulations; completes PGO tracking forms for Funding Opportunity Announcements and contracts; (9) reviews, approves, and tracks research protocols, clinical investigations, and the Food and Drug Administration (FDA) regulated response activities intended for submission to CDC Human Research Protections Office; (10) coordinates and tracks Office of Management and Budget (OMB) clearance under the Paperwork Reduction Act; (11) serves as authorized representative to/from FDA on all CDC Investigational New Drug (IND) protocols, Investigational Device Exemption applications, 510(k) applications, pre-Emergency Use Authorization (EUA) requests, and Drug Master File submissions; (12) centralizes and standardizes all CDC/FDA official correspondences; (13) drafts, reviews, prepares, and tracks all IND Protocols regulated by 21 CFR 312 and all pre-EUA documents; (14) develops and maintains standard operating procedures (SOP) and templates for processing non-research actions through the NCs to PGO; (15) monitors changes in grants management policies and procedures and adjusts SOPs as necessary; (16) liaises with PGO regarding general policies, procedures and forecasting; (17) organizes and coordinates logistics for panel reviews for non-research programs; (18) receives and reviews research proposals and initiates contact with technology transfer specialist; (19) negotiates terms of agreements with external parties; (20) reviews patent/intellectual property issues and potential conflicts of interest; (21) liaises with CCID organizations to advise, plan, coordinate, implement, manage, and oversee the allocation of additional or alternate laboratory, laboratory support, and laboratory office space; (22) plans and advises relocation into existing buildings and newly acquired laboratory, lab office, and lab support space; (23) serves as advisor to CCID management on issues of safety,

including biosafety, chemical safety, and radiation safety; (24) serves as the principal liaison to the OHS; (25) coordinates CCID safety program, working with all levels of CCID safety committees; and (26) monitors safety survey process and findings and ensures that all deficiencies are addressed in timely manner (remediation).

*Informatics (CVA33).* The mission of the CCID Informatics is to maximize the capacity for information technology to enhance the efficacy of infectious disease prevention. In carrying out its mission, Informatics: (1) Manages all IT project costs, schedules, performances, and risks; (2) provides expertise in leading application development techniques in information science and technology to effect the best use of resources; (3) performs technical evaluation and/or integrated baseline reviews of all information systems' products and services prior to procurement to ensure software purchases align with CCID strategy; (4) provides access to quality data in support of programmatic data analysis; (5) coordinates all enterprise-wide IT security policies and procedures with the office of the CDC Chief Information Security Officer; (6) ensures operations are in accordance with CDC Capital Planning and Investment Control guidelines; (7) ensures adherence to CDC enterprise architecture guidelines and standards; (8) consults with users to determine IT needs and to develop strategic and action plans; and (9) participates in the evolution, identification, development, or adoption of appropriate informatics standards in conjunction with the Coordinating Center for Health Information and Service.

*Enterprise Communications (CVA32).* The mission of the CCID Enterprise Communications (EC) is to lead CCID's support of the CDC Office of Enterprise Communication (OEC) in promoting public health and preventing disease through coordination and prompt response to urgent issues and concerns; recognition of issues requiring establishment or reevaluation of agency positions; safeguarding CCID and CDC credibility with, and confidence of, employees, partners and public; promotion and maintenance of effective and efficient communication networks. In carrying out its mission, CCID EC: (1) Organizes, develops, and implements employee communication activities; develops, writes, edits, and publishes articles about CCID employees and their work through a variety of channels; (2) provides channels for publicizing employee achievements and awards, program accomplishments, and

introducing new staff and management; (3) provides the central point of contact to CCID for the CCID Intranet; (4) provides a central point of reference for CCID announcements; (5) coordinates review and clearance of materials to be posted on CCID Intranet; (6) provides leadership in the development and branding of CCID's Intranet sites/pages; (7) assists the CCID and NC leadership in meeting their employee communication needs and priorities; (8) creates and maintains liaison with the CDC OEC, CDC Connects, and CCID NCs to share relevant employee communications information; (9) provides opportunities for two-way CCID employee communication, and timely and appropriate responses to inquiries and feedback from CCID employees; (10) conducts special projects as appropriate to develop feature CCID employee stories; (11) conducts employee research to enhance and improve CCID employee communication efforts including the CCID Intranet and other channels of employee communication; (12) provides employees access to information, services, activities, and materials that support or promote their health, morale, work efficiency, and sense of community; (13) serves as point of contact for controlled correspondence and other documents that require approval from the CCID Director and various other officials; (14) manages the flow of decision documents and correspondence for action by the CCID and NC directors; (15) coordinates collection and electronic management of CCID NC issues management materials; (16) ensures consistent application of CDC correspondence standards and styles; (17) coordinates CCID very important persons (VIP) visits and CCID lab tours for VIP visitors; (18) coordinates compilation of regularly updated CCID NC reports containing information on upcoming publications, activities, and other issues related to potential media opportunities, and CDC/ATSDR weekly legislative report for dissemination to CCID executive leadership team, CDC OEC, Coordinating Centers/Coordinating Offices (CC/CO), and NCs; (19) coordinates collection and electronic management of CCID and CCID NC issues management materials to include talking points, position papers, and others; (20) assists CCID NCs in meeting their press-related needs and priorities and provides or coordinates media training and technical assistance to CCID staff; (21) provides a central point of contact to CDC Division of Media Relations for CCID related media

requests and manages electronic files; and (22) provides a central point for CCID media monitoring.

*National Center for Immunization and Respiratory Diseases (CVG).* The National Center for Immunization and Respiratory Diseases (NCIRD) prevents disease, disability, and death through immunization and by control of respiratory and related diseases. In carrying out its mission, NCIRD: (1) Provides leadership, expertise, and service in laboratory and epidemiological sciences, and in immunization program delivery; (2) conducts applied research on disease prevention and control; (3) translates research findings into public health policies and practices; (4) provides diagnostic and reference laboratory services to relevant partners; (5) conducts surveillance and research to determine disease distribution, determinants, and burden nationally and internationally; (6) responds to disease outbreaks domestically and abroad; (7) ensures that public health decisions are made objectively and based upon the highest quality of scientific data; (8) provides technical expertise, education, and training to domestic and international partners; (9) provides leadership to internal and external partners for establishing and maintaining immunization, and other prevention and control programs; (10) develops, implements, and evaluates domestic and international public health policies; (11) communicates information to increase awareness, knowledge, and understanding of public health issues domestically and internationally, and to promote effective immunization programs; (12) aligns the national center focus with the overall strategic goals of CDC; and (13) implements, coordinates, and evaluates programs across NCIRD, CCID, and CDC to optimize public health impact.

*Office of the Director (CVG).* (1) Provides leadership, expertise, and service in laboratory and epidemiological sciences and in immunization program delivery; (2) provides diagnostic and reference laboratory services to relevant partnerships; (3) works with CCID OD to ensure spending plans, budget planning, and budget execution are in line with the overall infectious disease strategies and priorities; (4) ensures that the CCID strategy is executed by the divisions and aligned with overall CDC goals; (5) co-develops execution strategies for the center with the division directors; (6) provides program and science quality oversight; (7) builds leadership at the division and branch levels; (8) evaluates the strategies, focus, and prioritization

of the division research, program, and budget activities; (9) identifies and coordinates synergies between center and relevant partners; (10) ensures that policy development is consistent and appropriate; (11) facilitates research and program activities by providing leadership support; (12) proposes resource priorities throughout the budget cycle; (13) ensures scientific quality, ethics, and regulatory compliance; (14) fosters an integrated approach to research, program, and policy activities; (15) liaises with HHS and other domestic and international immunization and respiratory disease partners as well as with NCIRD divisions; and (16) coordinates center's emergency response activities related to immunization issues and complex acute respiratory infectious disease emergencies.

*National Center for Zoonotic, Vector-Borne, and Enteric Diseases (CVH).* The National Center for Zoonotic, Vector-Borne, and Enteric Diseases (NCZVED) maximizes public health and safety nationally and internationally through the elimination, prevention, and control of disease, disability, and death caused by suspected and confirmed zoonotic, vector-borne, foodborne, waterborne, mycotic, prion, and related infections. In carrying out its mission, NCZVED: (1) Provides leadership, expertise, and service in laboratory, medical, and epidemiological sciences throughout the world; (2) conducts applied research aimed to eliminate, prevent, and control disease; (3) translates research findings into public health policies, practices, and programs; (4) provides diagnostic and reference laboratory services to relevant partners; (5) conducts surveillance and research to determine disease distribution, disease determinants, and disease burden nationally and internationally; (6) responds to disease outbreaks domestically and abroad; (7) ensures that public health decisions are made objectively and based upon the highest quality of scientific data; (8) provides technical expertise, education, and training to domestic and international partners; (9) provides leadership to internal and external partners for establishing and maintaining screening, treatment, and other elimination, prevention, and control programs; (10) develops, implements, and evaluates domestic and international public health policies, practices, and programs; (11) communicates information to increase awareness, knowledge, and understanding of public health issues domestically and internationally; (12) aligns the national center focus with the

overall strategic goals of the CDC; (13) implements, coordinates, and evaluates programs across CDC, CCID, and NCZVED to optimize public health impact; (14) conducts bioterrorism preparedness activities to prevent or lessen the severity of bioterrorism incidents; (15) builds strategic partnerships with internal and external stakeholders; and (16) clarifies the dynamic link between animals, people, and the environment to maximize public health impact.

*Office of the Director (CVH1).* (1) Works with CCID OD to ensure spending plans, budget planning, and budget execution are in line with the overall CDC infectious disease strategies and priorities; (2) ensures that the CCID strategy is executed by the divisions and aligned with overall CDC goals; (3) co-develops execution strategies for the national center with the division directors; (4) provides program and science quality oversight; (5) builds leadership at the division and branch levels; (6) evaluates the strategies, focus, and prioritization of the division research, program, and budget activities; (7) identifies and coordinates synergies between the national center and relevant partners; (8) ensures that policy development is consistent and appropriate; (9) facilitates research and program activities by providing leadership support; (10) proposes resource priorities throughout the budget cycle; (11) ensures scientific quality, ethics, and regulatory compliance; (12) fosters an integrated approach to research, program, and policy activities; (13) liaises with HHS and partners concerning activities related to vector-borne, zoonotic, and enteric infectious diseases; and (14) ensures that programmatic goals are achieved with measurable impact.

*National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (CVJ).* The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) maximizes public health and safety nationally and internationally through the elimination, prevention, and control of disease, disability, and death caused by Human Immunodeficiency Virus Infection/Acquired Immunodeficiency Syndrome (HIV/AIDS), non-HIV retroviruses, viral hepatitis, other STDs, TB, and non-tuberculosis mycobacteria. In carrying out its mission, NCHHSTP: (1) Builds capacity and enhances public health infrastructure for preventing and treating HIV/AIDS, viral hepatitis, STDs, and TB domestically and internationally; (2) coordinates activities and programs across CDC and CCID in order to maximize the public health

impact of HIV/AIDS, viral hepatitis, STDs, and TB interventions; (3) conducts surveillance and research to determine the distribution, determinants, and burden of HIV/AIDS, viral hepatitis, STDs, and TB infections domestically and internationally; (4) conducts program evaluation to improve programs and activities relating to the prevention of HIV/AIDS, viral hepatitis, STDs, and TB, and determine their impact; (5) provides reference laboratory and clinical diagnostic services for HIV/AIDS, viral hepatitis, STDs, and TB to relevant stakeholders; (6) maximizes synergies among HIV/AIDS, viral hepatitis, STDs, and TB programs; domestically and internationally; (7) engages external partners to develop and implement effective HIV/AIDS, viral hepatitis, STDs, and TB policies, research, and programs; (8) engages partners to reduce health disparities among those affected by HIV/AIDS, viral hepatitis, STDs, and TB; (9) provides technical assistance and training to domestic and international partners in the diagnosis, treatment, and prevention of HIV/AIDS, viral hepatitis, STDs, and TB; (10) conducts domestic and international public health communication activities to disseminate research findings and increase awareness of HIV/AIDS, viral hepatitis, STDs, and TB; (11) conducts operational, behavioral, and biomedical research to improve the distribution, diagnosis, prevention, and control of HIV/AIDS, viral hepatitis, STDs, and TB; (12) provides scientific leadership regarding public health ethics and protection of human subjects linked to HIV/AIDS, viral hepatitis, STDs, and TB; (13) translates research findings into public health practice and policy for HIV/AIDS, viral hepatitis, STDs, and TB; (14) plans, coordinates, and guides programs and activities with external partners, federal agencies, and other organizations related to HIV/AIDS, viral hepatitis, STDs, and TB prevention, care, and treatment; (15) leads and participates in the development, implementation, and evaluation of domestic and international policies and guidelines related to HIV/AIDS, viral hepatitis, STDs, and TB; (16) provides scientific leadership regarding screening, treatment, immunization, and other prevention interventions relevant to HIV/AIDS, viral hepatitis, STDs, and TB; (17) assures all public health decisions are based on the highest quality scientific data, openly and objectively derived; (18) provides leadership to assist international partners in establishing and maintaining HIV/AIDS, viral hepatitis, STDs, and TB

screening, treatment, immunization, and other prevention and control programs; (19) assists countries in improving treatment, care, and support for people living with HIV/AIDS, and building capacity and infrastructure to address the global HIV/AIDS pandemic; (20) works with other federal agencies, governments of other nations, and other partners to implement the U.S. Government's international efforts to reduce the global burden of HIV/AIDS; (21) ensures that programmatic and scientific activities are aligned with, and in support of, CDC's overall mission, goals, and strategic imperatives; (22) allocates and tracks CDC resources and contributes to the development of CDC's short-, medium- and long-term strategic plans for preventing the spread of HIV/AIDS, viral hepatitis, STDs, and TB domestically and internationally; and (23) coordinates oversight of the NCHHSTP Federal Advisory Committees.

*Office of the Director (CVJ1).* (1) Provides leadership and guidance on the development of goals and objectives, policies, program planning and development, and program management and operations of the activities of the NCHHSTP, and manages, directs, coordinates, and evaluates the center's activities; (2) facilitates closer linkages between HIV, non-HIV retroviruses, STDs, viral hepatitis, TB, and non-TB mycobacteria surveillance activities and prevention programs at all levels, and facilitates collaboration, integration, and multi-disciplinary approaches to enhance the effectiveness of HIV, STD, viral hepatitis, and TB prevention programs; (3) facilitates integration of science and prevention programs throughout NCHHSTP and enhances the coordination and integration of HIV, STD, viral hepatitis, and TB prevention services for individuals and populations at increased risk for more than one of these infections; (4) coordinates the integration of CDC funding of state and local health departments for HIV, STD, viral hepatitis, and TB prevention; (5) facilitates and coordinates the assignment of field staff in accordance with CDC and NCHHSTP priorities and objectives; (6) provides technical information services to facilitate dissemination of relevant public health information and facilitates collaboration with national health activities, CDC components, other agencies and organizations, and foreign governments on international health activities; (7) provides oversight for the programmatic coordination of HIV, STD, viral hepatitis, and TB activities between NCHHSTP and other NCs; develops

recommendations to the CDC Director as the lead NC for these programs for the distribution of HIV, STD, viral hepatitis, and TB funds CDC-wide; and advises the Director, CDC, on other policy matters concerning NCHHSTP activities; (8) provides technical assistance to divisions on issues management, public affairs, and health communications strategies, and coordinates with external organizations, the news, public service, entertainment and other media to ensure effective findings and their implications for public health reach the public; (9) collaborates closely with divisions to produce materials designed for use by the news media; (10) secures appropriate clearance of these materials within NCHHSTP and CDC; (11) develops strategies and operational systems for the proactive dissemination of effective findings and their implications for prevention partners and the public, responds to public inquiries, and distributes information materials apart from the clearinghouses, hotlines, or other contractual mechanisms; (12) coordinates graphics and publishing services for NCHHSTP staff; reviews and prepares congressional testimony and briefing documents; and analyzes the implications of legislation and legislative proposals; (13) plans and coordinates the annual program planning process; (14) coordinates with OD, CC/COs, and divisions in determining and interpreting operating policy and in ensuring their respective management input for specific program activity plans; (15) interprets general policy directives and proposed legislation relating to NCHHSTP program goals and objectives, and coordinates the development and review of congressional reports; serves as the coordination point for Inspector General and General Accounting Office audits and reviews; (16) coordinates and manages external groups such as advisory committees and serves as central point for OMB clearances and controlled correspondence; (17) advises on activities that might affect other NC and provides leadership in the integration of health disparities goals, objectives, and strategies in the development of policies and programs of NCHHSTP; (18) coordinates and tracks health disparity activities within the center and provides leadership in support of research, surveillance, education, training, and program development to reduce health disparities; (19) develops partnerships with other federal agencies and nongovernmental organizations working on similarly-affected populations; (20) provides technical support and funding

to the Tuskegee University National Center for Bioethics in Research and Health Care and manages the Tuskegee Participants Health Benefits Program; (21) sponsors workgroups, meetings, and conferences related to health disparities and collaborates with the CDC Office of the Director, CC/COs, and other NCs on health disparity activities; (22) works with NCHHSTP leadership to promote a diverse public health workforce through internships, fellowships, training programs, and other activities; and (23) works with the CDC Office of Minority Health and Health Disparities to monitor progress in meeting the four Executive Orders related to improving minority health.

*National Center for Preparedness, Detection, and Control of Infectious Diseases (CVK).* The National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID) maximizes prevention, preparedness, and response to infectious diseases in order to protect populations domestically and internationally through leadership, partnerships, epidemiologic and laboratory studies, and the use of quality systems, standards, and practices. In carrying out its mission, NCPDCID: (1) Works collaboratively across CDC and with public health and healthcare partners in conducting, coordinating, and supporting surveillance, research, and prevention programs to prevent and minimize morbidity and mortality among domestic and international populations; (2) collaborates with other CDC programs to ensure availability of appropriate domestic and international platforms intended to build capacity and conduct public health work on infectious diseases; (3) coordinates activities across CCID and CDC related to vulnerable populations, healthcare quality, quarantine, research, surveillance, emerging infectious diseases, and laboratory services; (4) establishes relationships and partnerships with domestic and international health organizations, healthcare facilities, federal agencies, state and local health departments, and other external partners; (5) provides technical assistance to external partnerships for improving program operations; (6) provides a platform for synthesis, translation, and dissemination of research findings into public health practice at the front line; (7) participates in the development of national policies and guidelines for prevention and control of infectious diseases; (8) coordinates processes for developing, awarding, and managing grants and cooperative agreements; (9)

administers a national quarantine program to protect the U.S. against the introduction of diseases from foreign countries and the transmission of communicable disease between states; (10) facilitates appropriate cross-cutting collaboration with other NCs, CCID, other CDC programs, and external partners to promote effective surveillance for infectious threats to health; (11) designs and conducts epidemiologic studies to investigate the causes and risk factors for infectious diseases; (12) identifies, evaluates, and promotes the nationwide implementation of interventions designed to prevent infectious diseases, antimicrobial resistance, related adverse events, and medical errors among patients and healthcare personnel; (13) investigates and responds to outbreaks, emerging infections, and related adverse events among patients, healthcare providers, and others associated with the healthcare environment; (14) leads the improvement of domestic and international laboratory practices in clinical and public health laboratories through a quality systems approach; (15) provides services and expertise in development of quality systems to support compliance with FDA regulations on production, distribution, and use of laboratory diagnostic reagents; (16) provides support to CDC laboratories and investigators including provisions of animals, services, materials, and specialized expertise; and (17) provides emergency response coordination to CCID resources and enhanced epidemiologic, surveillance, and laboratory response capacity for bioterrorism and other infectious disease public health emergencies.

*Office of the Director (CVK1).* (1) Directs and manages the science, programs and activities of the NCPDCID; (2) provides leadership and coordination for the development and implementation of programs to enhance the prevention and control of infectious diseases nationally and internationally; (3) provides leadership and guidance on policy, program planning and development, program integration, management, and operations; (4) identifies and coordinates synergies between national centers and relevant partners; (5) provides technical information services to facilitate dissemination of relevant public health information; (6) provides liaison with other Governmental agencies and international organizations; (7) coordinates, in collaboration with the appropriate CCD and CDC components, international health activities relating to the prevention and control of infectious

diseases; (8) advises the Director CCID and the Director, CDC, on policy matters concerning NCPDCID programs and activities; (9) coordinates development and review or regulatory documents and congressional reports; and (10) analyzes health programs and proposed legislation with respect to NCPDCID programs, goals and objectives.

Dated: April 10, 2007.

**William H. Gimson,**

*Chief Operating Officer, Centers for Disease Control and Prevention (CDC).*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007N-0068]

#### Medical Device User Fee and Modernization Act; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting to discuss our proposed recommendations for the reauthorization of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA I) for fiscal years (FY) 2008 through 2012, as well as other proposals to improve the review of medical devices and the third party inspection program. These proposed recommendations were developed after discussions with the regulated industry. Section 105 of MDUFMA I directs FDA to publish these proposed recommendations in the **Federal Register**, hold a meeting at which the public may present its views on the recommendations, and provide for a period of 30 days for the public to provide written comments on the recommendations. The public meeting and comment period will provide an opportunity for public input on the proposed recommendations from all interested parties, including the regulated industry, scientific and academic experts, healthcare professionals, and representatives of patient and consumer advocacy groups.

**DATES:** The public meeting will be held on April 30, 2007, from 12 noon to 5 p.m. Registration to attend and to present at the meeting must be received by April 25, 2007. (See section III.B of this document for details on registration.) Submit written comments by May 18, 2007. Transcripts will be

available approximately 30 days after the meeting. (See section III.C of this document for more details on transcript availability.)

**ADDRESSES:** The public meeting will be held at the Food and Drug Administration, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** For information regarding this notice, contact: Erik Mettler, Office of Policy and Planning, Food and Drug Administration (HF-11), 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360, FAX: 301-594-6777, e-mail: [Erik.Mettler@fda.hhs.gov](mailto:Erik.Mettler@fda.hhs.gov).

For information regarding registration, contact: Cynthia Garris, Office of Communication, Education, and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration (HFZ-220), 1350 Piccard Ave., Rockville, MD 20850, phone: 240-276-3150 ext. 121, FAX: 240-276-3151; e-mail: [cynthia.garris@fda.hhs.gov](mailto:cynthia.garris@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

MDUFMA I (Public Law 107-250, October 26, 2002) amended the Federal Food, Drug, and Cosmetic Act (the act) to provide FDA with the following new responsibilities and resources:

- User fees for premarket reviews of certain device premarket applications (see sections 737 and 738 of the act (21 U.S.C. 379i and 379j));
- Performance goals to improve medical device reviews (see section 101(3) of MDUFMA I and section 738(g)(1) of the act);
- Establishment inspections to be conducted by accredited third-parties when certain conditions are met (see section 704(g) of the act (21 U.S.C. 374)); and
- Improved oversight and coordination of reviews of combination products (products that combine devices, drugs, or biologics) (see section 503(g) of the act (21 U.S.C. 353(g))).

##### A. Medical Device User Fees and Performance Goals

In the years prior to MDUFMA I, FDA's resources for our device and radiological health programs had increased at a lower rate than FDA's