

Management Analysis and Services Office, CDC, pursuant to Pub. L. 92-463.

Agenda items are subject to change as priorities dictate.

Name: Subcommittee on Intimate Partner Violence and Sexual Assault (SIPVSA).

Time and Date: 10 a.m.–11:30 a.m., June 8, 2005.

Place: Crowne Plaza Hotel Atlanta-Buckhead, 3377 Peachtree Road, NE., Atlanta, GA 30326.

Status: Open to the public, limited only by the space available.

Purpose: To advise and make recommendations to the full advisory committee and the Director, NCIPC, regarding feasible goals for prevention and control of domestic and sexual violence. The SIPVSA will make recommendations regarding strategies, objectives, and priorities in programs, policies and research.

Matters To Be Discussed: The SIPVSA will discuss strategies for examining models for integration of intimate partner violence and sexual assault prevention into broader public health infrastructure and strategies.

Name: Advisory Committee for Injury Prevention and Control.

Time and Dates:

1 p.m.–5:30 p.m., June 8, 2005;

8:30 a.m.–3:30 p.m., June 9, 2005.

Place: Crowne Plaza Hotel Atlanta-Buckhead, 3377 Peachtree Road, NE., Atlanta, GA 30326.

Status:

Closed: 1 p.m.–1:45 p.m., June 8, 2005.

Open: 1:45 p.m.–5:30 p.m., June 8, 2005;

Open: 8:30 a.m.–3:30 p.m., June 9, 2005.

Purpose: The Committee advises and makes recommendations to the Secretary, Health and Human Services, the Director, CDC, and the Director, NCIPC, regarding feasible goals for the prevention and control of injury. The Committee makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury prevention and control.

Matters To Be Discussed: Prior to the full committee meeting, there will be a brief meeting conducted by conference call of the Working Group on Injury Control and Infrastructure Enhancement, a group formed to report to the full committee identifying gaps and suggesting ways to enhance injury prevention efforts.

The working group will focus on defining injury infrastructure and developing a simple mechanism to assess current efforts underway throughout the injury field to enhance that infrastructure. Starting at 1 p.m., June 8, through 1:45 p.m., the full committee will vote on the results of secondary review. This portion of the meeting will be closed to the public in accordance with provisions set forth in section 552(b)(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. Following the closed session, the meeting will open to the public for an update on Center activities from the Director, NCIPC; reports from the Subcommittees and Working Group; state infrastructure development; and

discussion on how NCIPC can support the recommendations of CDC's Futures Initiative.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: Ms. Louise Galaska, Executive Secretary, ACIPC, NCIPC, CDC, 4770 Buford Highway, NE., M/S K02, Atlanta, Georgia 30341-3724, telephone (770) 488-4694.

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 21, 2005.

B. Kathy Skipper,

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

[FR Doc. 05-8499 Filed 4-27-05; 8:45 am]

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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

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) announce the following meeting:

Name: National Center for Injury Prevention and Control (NCIPC) Initial Review Group (IRG).

Times and Dates:

1 p.m.–5:30 p.m., May 23, 2005;

8:30 a.m.–5:30 p.m., May 24, 2005;

8:30 a.m.–5:30 p.m., May 25, 2005.

Place: The Initial Review Group will originate at the Hilton Atlanta Airport and Towers, 1031 Virginia Avenue, Atlanta, Georgia 30354.

Status:

Open: 1 p.m.–1:30 p.m., May 23, 2005.

Closed: 1:30 p.m.–5:30 p.m., May 23, 2005;

Closed: 8:30 a.m.–5:30 p.m., May 24, 2005;

Closed: 8:30 a.m.–5:30 p.m., May 25, 2005.

Purpose: This group is charged with providing advice and guidance to the Secretary 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 and supports Injury Control Research Centers (ICRCs).

Matters To Be Discussed: Agenda items include an overview of the injury program, discussion of the review process and panelists' responsibilities, and the review of and vote on applications. Beginning at 1:30

p.m., May 23, through 5:30 p.m., May 25, the Group will review individual research cooperative agreement in response to announcement: #05018, Cooperative Agreement Program for the National Academic Centers of Excellence. This meeting will be closed to the public in accordance with provisions set forth in section 552(b)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Pub. L. 92-463.

Agenda items are subject to change as priorities dictate.

For More Information Contact: Gwendolyn H. Cattledge, Ph.D., M.S.E.H., Executive Secretary, NCIPC IRG, CDC, 4770 Buford Highway, NE., M/S K02, Atlanta, Georgia 30341-3724, telephone (770) 488-4655.

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 21, 2005.

B. Kathy Skipper,

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

[FR Doc. 05-8500 Filed 4-27-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Environmental Health/Agency for Toxic Substances and Disease Registry

The Board of Scientific Counselors (BSC), Centers for Disease Control and Prevention (CDC), National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR).

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) and the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (ATSDR) announce the following committee meeting:

Name: Board of Scientific Counselors, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

Times and Dates: 8:30 a.m.–5 p.m., May 19, 2005. 8 a.m.–12:15 p.m., May 20, 2005.

Place: CDC facility, 1825 Century Boulevard, Atlanta, GA 30345.

Status: Open to the public for observation, limited only by the space available. The meeting room

accommodates approximately 100 people.

Purpose: The Secretary, and by delegation, the Director of the Centers for Disease Control and Prevention and the Administrator of the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry, are authorized under section 301(42 U.S.C. 241) and section 311 (42 U.S.C. 243) of the Public Health Service Act, as amended, to (1) conduct, encourage, cooperate with, and assist other appropriate public authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and other impairments; (2) assist states and their political subdivisions in the prevention of infectious diseases and other preventable conditions and in the promotion of health and well being; and (3) train state and local personnel in health work. The Board of Scientific Counselors, NCEH/ATSDR provides advice and guidance to the Secretary, HHS; the Director, CDC and Administrator, ATSDR; and the Director, NCEH/ATSDR, regarding program goals, objectives, strategies, and Priorities in fulfillment of the agencies' mission to protect and promote people's health. The Board provides advice and guidance that will assist NCEH/ATSDR in ensuring scientific quality, timeliness, utility, and dissemination of results. The Board also provides guidance to help NCEH/ATSDR work more efficiently and effectively with its various constituents and to fulfill its mission in protecting America's health.

Matters to be Discussed: The agenda items for the meeting on May 19–20, 2004, will include but are not limited to an update on future initiatives for Environmental Health and Injury Prevention; presentation on Places Goals and Research Agenda; an update on the state of NCEH/ATSDR; review of the ATSDR Draft Dioxin Soil Policy Guideline; presentation on asbestos; discussion on the criteria for “De-Listing” chemicals from the CDC's National Report on Human Exposure to Environmental Chemicals; a discussion on the 3rd National Report on Human

Exposure to Environmental Chemicals and updates by the subcommittees and workgroup.

Agenda items are tentative and subject to change.

Contact Person for More Information: Individuals interested in attending the meeting, please contact Sandra Malcom, Committee Management Specialist, NCEH/ATSDR, 1600 Clifton Road, Mail Stop E–28, Atlanta, GA 30303; telephone (404) 498–0003, Fax (404) 498–0059; e-mail: smalcom@cdc.gov. The deadline for notification of attendance is May 13, 2005.

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 National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

Dated: April 21, 2005.

B. Kathy Skipper,

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

[FR Doc. 05–8497 Filed 4–27–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0143]

High Chemical Co. et al.; Proposal to Withdraw Approval of 13 New Drug Applications; Opportunity for a Hearing; Reissuance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reissuance.

SUMMARY: The Food and Drug Administration (FDA) is reissuing the notice announcing an opportunity to request a hearing on the agency's proposal to withdraw approval of 13 new drug applications (NDAs) from multiple sponsors. The basis for the proposal is that the sponsors have repeatedly failed to file required annual reports for these applications. In the **Federal Register** of January 28, 2005 (70

FR 4134), FDA published a notice announcing an opportunity for a hearing on the agency's proposal to withdraw approval of 13 NDAs from multiple sponsors. That notice published with an inadvertent error; in a document published elsewhere in this issue of the **Federal Register**, the agency is withdrawing that notice.

DATES: Submit written requests for a hearing by May 31, 2005; submit data and information in support of the hearing request by June 27, 2005.

ADDRESSES: Requests for a hearing, supporting data, and other comments are to be identified with Docket No. 2005N–0143 to be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Florine P. Purdie Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: FDA is reissuing the notice announcing an opportunity to request a hearing on the agency's proposal to withdraw approval of 13 new drug applications (NDAs) from multiple sponsors. The basis for the proposal is that the sponsors have repeatedly failed to file required annual reports for these applications. In the **Federal Register** of January 28, 2005 (70 FR 4134), FDA published a notice announcing an opportunity for a hearing on the agency's proposal to withdraw approval of 13 NDAs from multiple sponsors. That notice published with an inadvertent error; in a document published elsewhere in this issue of the **Federal Register**, the agency is withdrawing that notice.

The holders of approved applications to market new drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81). The holders of the approved applications listed in the following table have failed to submit the required annual reports and have not responded to the agency's request by certified mail for submission of the reports.