

the role of amplification; models of early intervention; and the need for future research.

Agenda items are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT:

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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: May 20, 2005.

Alvin Hall,

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 Institute for Occupational Safety and Health, Safety and Occupational Health Study Section

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 committee meeting.

Name: Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH).

Times and Dates: 8 a.m.–5 p.m., June 21, 2005. 8 a.m.–5 p.m., June 22, 2005.

Place: Embassy Suites Hotel, 1900 Diagonal Road, Alexandria, Virginia, 22314, telephone 703/684-5900, fax 703/684-1403.

Status: Open 8 a.m.–8:15 a.m., June 21, 2005. Closed 8:15 a.m.–5 p.m., June 21, 2005. Closed 8 a.m.–5 p.m., June 22, 2005.

Purpose: The Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) received in response to the Institute's standard grants review and funding cycles pertaining to research issues in occupational safety and health, and allied areas.

It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute's program goals. This will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects, which will lead to

improvements in the delivery of occupational safety and health services, and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals.

Matters to be Discussed: The meeting will convene in open session from 8–8:15 a.m. on June 21, 2005, to address matters related to the conduct of Study Section business. The remainder of the meeting will proceed in closed session. The purpose of the closed sessions is for the study section to consider safety and occupational health-related grant applications. These portions of 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, Centers for Disease Control and Prevention, pursuant to Section 10(d) Pub. L. 92-463.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: Price Connor, Ph.D., NIOSH Health Scientist, 1600 Clifton Road, NE., Mailstop E-74, Atlanta, Georgia 30333, telephone 404/498-2511, fax 404/498-2569.

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Dated: May 20, 2005.

Alvin Hall,

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. 2005D-0169]

Draft Guidance on Useful Written Consumer Medication Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Useful Written Consumer Medication Information (CMI)." CMI is written information developed for consumers about prescription drugs that is distributed to consumers when they have prescriptions filled. The guidance discusses general issues and makes recommendations on the content of useful written CMI.

DATES: Submit written or electronic comments on the draft guidance by July 25, 2005. General comments on agency

guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Ellen Tabak, Center for Drug Evaluation and Research (HFD-410), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7843.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled "Useful Written Consumer Medication Information (CMI)." This draft guidance is intended to assist individuals or organizations (e.g., pharmacies, private vendors, healthcare associations) in developing useful written CMI. CMI is written information about prescription drugs developed by organizations or individuals, other than a drug's manufacturer, that is intended for distribution to consumers at the time of dispensing. Since neither FDA nor the drug's manufacturer reviews or approves CMI, FDA recommends that the developers of written medication information use the factors discussed in this guidance to ensure that their CMI is useful to consumers.

Traditionally, FDA has believed that when people are well-informed about the medications they take, they are able to make better decisions about their healthcare and better use of the prescription medications available to them. Access to useful written information about prescription medications is important to ensuring appropriate use of these products. In 1996, a steering committee comprised of interested stakeholders (including healthcare professionals, consumer organizations, voluntary health agencies, pharmaceutical manufacturers, prescription drug wholesalers, drug information database companies, CMI developers, and