

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of research grant applications in response to Development and Testing of a Coal Mine Safehouse, Program Announcement PA 04-038.

For More Information Contact: George Bokosh, Designated Federal Official, 626 Cochran Mill Road, Pittsburgh, PA 15236, telephone (412) 386-6465.

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: September 21, 2006.

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

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

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), The Centers for Disease Control and Prevention, NCEH/ATSDR announces the following subcommittee teleconference meeting:

Name: Health Department Subcommittee (HDS).

Time and Date: 1 p.m.-2:30 p.m., October 16, 2006.

Place: Century Center, 1825 Century Boulevard, Atlanta, Georgia 30345.

Status: Open to the public, teleconference access limited only by availability of telephone ports.

Purpose: Under the charge of the Board of Scientific Counselors, NCEH/ATSDR the Health Department Subcommittee will provide the BSC, NCEH/ATSDR with advice and recommendations on local and state health department issues and concerns that pertain to the mandates and mission of NCEH/ATSDR.

Matters To Be Discussed:

The meeting agenda will include a follow-up on Workforce Recommendations; a selection of FY 2007/2008 Environmental Public Health Program Priorities; and the next steps for the Health Department

Subcommittee. Items are subject to change as priorities dictate.

Supplementary Information: This teleconference meeting is scheduled to begin at 1 p.m. Eastern Standard Time. To participate during the Public Comment period (2-2:10 p.m. Eastern Standard Time), dial (877) 315-6535 and enter conference code 383520.

For More Information Contact: Individuals interested in attending the meeting, please contact Shirley D. Little, 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: slittle@cdc.gov.

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Dated: September 21, 2006.

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. 2006N-0378]

Review of Agreements, Guidances, and Practices Specific to Assignment of Combination Products in Compliance With the Medical Device User Fee and Modernization Act of 2002; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (the act) requires the Food and Drug Administration (FDA) to review each agreement, guidance, or practice that is specific to the assignment of combination products to agency centers and to determine whether the agreement, guidance, or practice is consistent with the requirements of the act. In carrying out the review, the agency is to consult with stakeholders and directors of the agency centers, and then determine whether to continue in effect, modify, revise, or eliminate such an agreement, guidance, or practice. The agency has completed its initial review of relevant agreements, guidances, and practices, and has consulted with directors of the agency centers. This document provides the preliminary results of the agency's

review and requests stakeholder comments to fulfill the act's requirement for stakeholder consultation prior to the agency's final determination whether to continue the agreements, guidance, or practices in effect, or to modify, revise, or eliminate them.

DATES: Submit written or electronic comments by November 27, 2006.

ADDRESSES: 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>.

FOR FURTHER INFORMATION CONTACT: Suzanne O'Shea, Office of Combination Products (HFG-3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301-427-1934, FAX: 301-427-1935, e-mail: suzanne.oshea@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In October 2002, the Medical Device User Fee and Modernization Act (MDUFMA) added section 503(g)(4)(F) (21 U.S.C. 353(g)(4)(F)) to the act. This new provision requires the Secretary of the Department of Health and Human Services (the Secretary), acting through the Office of Combination Products (OCP), to review each agreement, guidance, or practice of the Secretary that is specific to the assignment of combination products to agency centers and to determine whether the agreement, guidance, or practice is consistent with the requirements of section 503(g) of the act. In carrying out such a review, OCP is to consult with stakeholders and the directors of the agency centers. After such consultation, OCP is to determine whether to continue in effect, modify, revise, or eliminate such agreement, guidance, or practice, and publish in the **Federal Register** a notice of the availability of any modified or revised agreement, guidance, or practice.

This notice provides the preliminary results of OCP's review of agreements, guidances, and practices that were in effect at the time section 503(g)(4)(F) of the act was enacted for their consistency with the act's requirement for the prompt assignment of combination products to agency centers on the basis of the products' primary mode of action (PMOA).¹ The directors of relevant

¹ Section 503(g)(1) of the act requires that combination products be assigned to an agency center for regulation and review on the basis of the product's PMOA. In addition, section 503(g)(4)(B) of the act directs OCP to ensure the prompt