

(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 applications received in response to Cooperative Agreements Program Announcement Number 00075, Association of American Medical Colleges, Program Announcement Number 99122, Association of Schools of Public Health, and Program Announcement Number 97014, Association of Teachers of Preventive Medicine, Research Project Areas—Panel 1.

*For Further Information Contact:*

Joan Karr, PhD, Scientific Review Administrator, Public Health Practice Program Office, Centers for Disease Control, 4770 Buford Highway, NE., MS-K38, Atlanta, GA 30341, Telephone 770.488.2597.

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 17, 2004.

**Alvin Hall,**

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

[FR Doc. 04-11534 Filed 5-20-04; 8:45 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 (SEP): Cooperative Agreements Program Announcement Number 00075, Association of American Medical Colleges, Program Announcement Number 99122, Association of Schools of Public Health, and Program Announcement Number 97014, Association of Teachers of Preventive Medicine, Research Project Areas—Panel 4

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 meeting:

*Name:* Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements Program Announcement Number 00075, Association of American Medical Colleges, Program Announcement Number 99122, Association of Schools of Public Health, and Program Announcement Number 97014,

Association of Teachers of Preventive Medicine, Research Project Areas—Panel 4.

*Times and Dates:* 7 p.m.–7:30 p.m., June 10, 2004 (Open). 7:30 p.m.–10 p.m., June 10, 2004 (Closed). 8 a.m.–5 p.m., June 11, 2004 (Closed).

*Place:* Sheraton Midtown Atlanta Hotel at Colony Square, 188 14th Street at Peachtree, Atlanta, GA 30361, Telephone 404.892.6000.

*Status:* Portions 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.

*Matters To Be Discussed:* The meeting will include the review, discussion, and evaluation of applications received in response to Cooperative Agreements Program Announcement Number 00075, Association of American Medical Colleges, Program Announcement Number 99122, Association of Schools of Public Health, and Program Announcement Number 97014, Association of Teachers of Preventive Medicine, Research Project Areas—Panel 4.

*Contact Person for More Information:* Joan F. Karr, Ph.D., Scientific Review Administrator, Public Health Practice Program Office, Centers for Disease Control, 4770 Buford Highway, NE., MS-K38, Atlanta, GA 30341, Telephone 770.488.2597.

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Dated: May 17, 2004.

**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. 2003D-0538]

#### Guidance for Industry and Food and Drug Administration Staff: Food and Drug Administration and Industry Actions on Premarket Notification Submissions: Effect on Food and Drug Administration Review Clock and Performance Assessment; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “FDA and Industry Actions on

Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment.” This guidance describes how FDA will assess its performance in the premarket notification (510(k)) program relative to the goals that accompany the authorization of medical device user fees. This guidance document is immediately in effect, but it remains subject to comment in accordance with the agency’s good guidance practices (GGPs).

**DATES:** Submit written or electronic comments on this guidance at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5” diskette of the guidance document entitled “FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

*For device issues:* Heather Rosecrans, Center for Devices and Radiological Health (HFZ-404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190, ext. 143.

*For biologics issues:* Leonard Wilson, Center for Biologics Evaluation and Research (CBER) (HFM-25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), signed into law on October 26, 2002, allows FDA to assess user fees for certain premarket reviews. Performance goals, referenced in the statute, accompany the authorization of medical device user fees. These goals represent a realistic