

and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Special Emphasis Panel; EUREKA.

*Date:* November 8, 2010.

*Time:* 8 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Amalfi Hotel, 200 West Kinzie Street, Chicago, IL 60654.

*Contact Person:* William C. Benzing, PhD, Scientific Review Administrator, Scientific Review Branch, DHHS/NIH/NINDS/DER/SRB, Neuroscience Center, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892, 301-496-0660, [Benzingw@mail.nih.gov](mailto:Benzingw@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: September 10, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-23268 Filed 9-16-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel Fellowships and Dissertations.

*Date:* October 13, 2010.

*Time:* 11 a.m. to 12:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Enid Light, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6132, MSC 9608, Bethesda, MD 20852, 301-443-3599, [elight@mail.nih.gov](mailto:elight@mail.nih.gov).

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel Developing & Advance Centers for Intervention and Services Research.

*Date:* October 22, 2010.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

*Contact Person:* Francois Boller, MD, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6142, MSC 9606, Bethesda, MD 20892-9606, 301-443-1513, [bollefr@mail.nih.gov](mailto:bollefr@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: September 10, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)—Ethics Subcommittee (ES)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the CDC announces the following meeting of the aforementioned subcommittee:

*Times and Dates:* 1 p.m.–5 p.m., October 7, 2010; 8:30 a.m.–12:30 p.m., October 8, 2010.

*Place:* CDC, Thomas R. Harkin Global Communications Center, Distance Learning Auditorium, 1600 Clifton Road, NE., Atlanta, GA 30333. This meeting is also available by teleconference. Please dial (877) 928-1204 and enter code 4305992.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 60 people. To accommodate public participation in the meeting, a conference telephone line will be available. The public is welcome to participate during the public comment. The

public comment periods are tentatively scheduled for 4 p.m.–4:15 p.m. on October 7, 2010 and from 12 p.m.–12:15 p.m. on October 8, 2010.

*Purpose:* The ES will provide counsel to the ACD, CDC, regarding a broad range of public health ethics questions and issues arising from programs, scientists and practitioners.

*Matter To Be Discussed:* Agenda items will include the following topics: Plans for obtaining public comment on the ventilator guidance document; efforts to support state, tribal, local and territorial health departments address ethical issues in the practice of public health; and ethical issues relating to patient notification following infection control lapses.

The agenda is subject to change as priorities dictate.

*Contact Person for More Information:* For security reasons, members of the public interested in attending the meeting should contact Drue Barrett, PhD, Designated Federal Official, ACD, CDC-ES, 1600 Clifton Road, NE., M/S D-50, Atlanta, Georgia 30333. Telephone (404) 639-4690. E-mail: [d Barrett@cdc.gov](mailto:d Barrett@cdc.gov). The deadline for notification of attendance is October 1, 2010.

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 10, 2010.

**Elaine L. Baker,**

*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

#### NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2010

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of Final Document.

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the publication of the following document entitled "NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2010." The document can be found at

<http://www.cdc.gov/niosh/docs/2010-167/>.

**Background:** The NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings was published in September 2004 (<http://www.cdc.gov/niosh/docs/2004-165/>). From that time until June 2007, approximately 60 new drugs have received FDA approval and approximately 60 drugs have received special warnings (usually black box warnings) based on reported adverse effects in patients. An additional 18 drugs were included from the updated NIH Hazardous Drug List. From this list of approximately 150 drugs, 62 drugs were determined to have one or more characteristic of a hazardous drug and published for comment in NIOSH Docket Number 105.

After expert panel review, public review and comment, input from stakeholders and review of the scientific literature NIOSH proposed a second, draft list of hazardous drugs that was published in NIOSH Docket 105A. The second, draft list identified 24 drugs that fit the NIOSH definition of hazardous drugs. The second draft list also proposed removing Bacillus Calmette-Guerin (BCG), based on additional comments received by NIOSH.

Following the second Federal Register Notice, BCG was reinstated to the list and a total of 21 new drugs were added to the 2004 list in Appendix A of the Alert.

This guidance document does not have the force and effect of law.

**FOR FURTHER INFORMATION CONTACT:** Barbara MacKenzie, NIOSH, Robert A. Taft Laboratories, 4676 Columbia Parkway, MS-C26, Cincinnati, OH 45226, Telephone (513) 533-8132, e-mail [hazardousdrugs@cdc.gov](mailto:hazardousdrugs@cdc.gov).

**Reference:** NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2010. Web address for this document: <http://www.cdc.gov/niosh/docs/2010-167/>.

**John Howard,**

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2010-23239 Filed 9-16-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

#### Food and Drug Administration

[Docket No. FDA-2010-N-0308]

#### Parallel Review of Medical Products

**AGENCIES:** Centers for Medicare and Medicaid Services; Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) are considering establishing a process for overlapping evaluations of premarket, FDA-regulated medical products when the product sponsor and both agencies agree to such parallel review. This process will serve the public interest by reducing the time between FDA marketing approval or clearance decisions and CMS national coverage determinations (NCDs). The agencies are establishing a docket to receive information and comment from the public on what products would be appropriate for parallel review by the two agencies, what procedures should be developed, how a parallel review process should be implemented, and other issues related to the effective operation of the process. The agencies are also announcing their intent to create a pilot program for parallel review of medical devices. The pilot program will begin after both agencies have reviewed the public comments on this notice. A memorandum of understanding (MOU) concerning the exchange of data and information has been completed between the two agencies. See <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm217585.htm>.

**DATES:** Submit either electronic or written comments by December 16, 2010.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** *General questions about parallel review:* Peter Beckerman, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4830, e-mail:

[peter.beckerman@fda.hhs.gov](mailto:peter.beckerman@fda.hhs.gov), or Tamara Syrek Jensen, Centers for Medicare and Medicaid Services, 7500 Security Blvd., Baltimore, MD 21244, e-mail: [Tamara.Syrekjensen@cms.hhs.gov](mailto:Tamara.Syrekjensen@cms.hhs.gov).

*For device sponsors interested in requesting voluntary parallel review:* Markham C. Luke, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-5550, e-mail: [markham.luke@fda.hhs.gov](mailto:markham.luke@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA and CMS share a common interest in improving the health of patients through the availability of safe, effective, and affordable medical products and fostering medical product innovations.

The mission of the FDA is to protect and promote the public health. It accomplishes this task, in part, by the following:

- Assuring the safety, efficacy, and quality of human drugs, biological products, and medical devices;
- Fostering innovations to make medical products safer and more effective; and
- Helping health care providers and the public get the accurate, science-based information they need to use medical products to improve public health.

The mission of CMS is to ensure effective, up-to-date Medicare coverage and to promote the continual improvement of the quality care for its beneficiaries. CMS accomplishes this mission by continuing to transform and modernize America's health care system, in part, by the following:

- Fostering accurate and predictable payments,
- Ensuring high-value health care,
- Promoting understanding of CMS programs among beneficiaries, the health care community, and the public.

Through coordinated decisions regarding medical products, FDA and CMS can affect public health in critical ways: FDA in determining the safety and effectiveness of those products and CMS in providing beneficial coverage and appropriate payment for covered items and services involving those products. Both agencies believe they should address the growing need to improve public health by speeding consumer access to and spurring the development of new, affordable, reliable, safer, and more effective medical products and services. FDA and