

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 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 guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Abigail C. Jacobs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6484, Silver Spring, MD 20993-0002, 301-796-0174.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled "Nonclinical Safety Evaluation of Drug or Biologic Combinations." This guidance provides recommendations on nonclinical approaches to support the clinical study and approval of FDCs, co-packaged products, and some adjunctive therapies. The intent of this guidance is to delineate general guiding principles.

In the **Federal Register** of January 26, 2005 (70 FR 3714), FDA announced the availability of a draft guidance entitled "Nonclinical Safety Evaluation of Drug Combinations." This notice gave interested persons an opportunity to submit comments. As a result of the comments, certain sections of this guidance have been reworded to improve clarity. Additionally, the following revisions have been made to the guidance: (1) The inclusion of combinations of biologics regulated by the Center for Drug Evaluation and Research and drugs, (2) a narrowing of the description of "adjunctive therapies" covered by the guidance, and (3) a clarification of the aspects of the developmental reproductive toxicology sections.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on nonclinical safety evaluation of drug and biologic combinations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the

requirements of the applicable statutes and regulations.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: March 7, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-3713 Filed 3-14-06; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Cancer Institute; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting 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 Cancer Institute Initial Review Group, Subcommittee E—Cancer Epidemiology, Prevention & Control.

*Date:* April 9-10, 2006.

*Time:* 6 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Marriott Bethesda North Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

*Contact Person:* Hasnaa Shafik, MD, Ph.D., Scientific Review Administration, Division of Extramural Activities, RPRB, National Cancer Institute, National Institutes of Health, 6116 Executive Blvd., Room 8037, Bethesda, MD 20892, (301) 451-4757, [shafikh@mail.nih.gov](mailto:shafikh@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 8, 2006.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 06-2523 Filed 3-14-06; 8:45 am]

**BILLING CODE 4140-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Center for Research Resources; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting 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 Center for Research Resources Special Emphasis Panel, Isel Cell Resource SEP.

*Date:* March 30-31, 2006.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:* Mohan Viswanathan, Ph.D., Deputy Director, Office of Review, NCCR, National Institutes of Health, 6701 Democracy Blvd., Room 1084, MSC 4874, 1 Democracy Plaza, Bethesda, MD 20892-4874, 301-435-0829, [mv10f@nih.gov](mailto:mv10f@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure; 93.306, 93.333, National Institutes of Health, HHS)

Dated: March 8, 2006.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 06-2524 Filed 3-14-06; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting 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 Eye Institute Special Emphasis Panel, NEI CDA Review Panel.

*Date:* March 29, 2006.

*Time:* 2 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Houmam H. Araj, PhD., Scientific Review Administrator, Division of Extramural Research, National Eye Institute, NIH, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892-9602, (301) 451-2020, [haraj@mail.nih.gov](mailto:haraj@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: March 8, 2006.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 06-2515 Filed 3-14-06; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Human Genome Research Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Inherited

Disease Research Access Committee, April 27, 2006, 8:30 a.m. to April 27, 2006, 5 p.m., George Washington University Inn, 824 New Hampshire Avenue, NW., Washington, DC 20037 which was published in the **Federal Register** on February 15, 2006, 71 FRN 7981.

The meeting of the Center for Inherited Disease Research Access Committee will also include a session on April 26, 2006, from 7 p.m. to 10 p.m. at The George Washington University Inn. The meeting is closed to the public.

Dated: March 8, 2006.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 06-2521 Filed 3-14-06; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting 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 Genome Research Institute Special Emphasis Panel, Genomic Database.

*Date:* April 10, 2006.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Ken D. Nakamura, PhD., Scientific Review Administrator, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Suite 4076, MSC 9306, Rockville, MD 20852, 301-402-0838. (Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS).

Dated: March 8, 2006.

**Anna Snouffer,**

*Acting Director, Office of Federal advisory Committee Policy.*

[FR Doc. 06-2522 Filed 3-14-06; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provision set forth in section 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 Biomedical Imaging and Bioengineering Special Emphasis Panel, ZEB1 OSC-CM.

*Date:* April 10, 2006.

*Time:* 8 a.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact of Persons:* Prabha L. Atreya, PhD., Scientific Review Administrator, Office of Scientific Review, National Institutes of Biomedical Imaging and Bioengineering, Bethesda, MD 20892, (301) 435-8633, [atreyapr@mail.nih.gov](mailto:atreyapr@mail.nih.gov).

Dated: March 8, 2006.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 06-2516 Filed 3-14-06; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice