

basis for these guidance documents establish requirements for all covered activities. For this reason, FDA strongly recommends that affected parties consult the regulations at 21 CFR part 1, subparts H and I, in addition to reading these SECGs.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding these SECGs. 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 applicable docket number(s) found in brackets in the heading of this document. 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 these SECGs at <http://www/cfsan.fda.gov/guidance.html>.

Dated: December 3, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-30738 Filed 12-11-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of 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 a meeting of the President's Cancer Panel.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C., as amended because the premature disclosure of other and the discussions would likely to significantly frustrate implementation of recommendations.

*Name of Committee:* President's Cancer Panel.

*Date:* January 5-6, 2004.

*Open:* January 5, 2004, 8 a.m. to 3:15 p.m.

*Agenda:* Living Beyond Cancer: Survivorship Issues and Challenges Among Older Adult Cancer Survivors.

*Place:* Lowes Philadelphia Hotel, 1200 Market Street, Philadelphia, PA 19107.

*Open:* January 5, 2004, 7 p.m. to 9 p.m.

*Agenda:* Town Hall Meeting.

*Place:* Lowes Philadelphia Hotel, 1200 Market Street, Philadelphia, PA 19107.

*Closed:* January 6, 2004, 9 a.m. to 12 p.m.

*Agenda:* To review and evaluate the Panel will supplement its public hearings with discussion of prepublication manuscripts on adult cancer survivorship.

*Place:* Lowes Philadelphia Hotel, 1200 Market Street, Philadelphia, PA 19107.

*Contact Person:* Maureen O. Wilson, PhD, Executive Secretary, National Cancer Institute, National Institutes of Health, 31 Center Drive, Building 31, Room 3A18, Bethesda, MD 20892, 301/496-1148.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <http://www.deainfo.nci.nih.gov/advisory/pcp/pcp.htm>, where an agenda and any additional information for the meeting will be posted when available.

(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: December 8, 2003.

**Anna P. Snouffer,**

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

[FR Doc. 03-30818 Filed 12-11-03; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood 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:* Heart, Lung, and Blood Initial Review Group, Clinical Trials Review Committee.

*Date:* February 23, 2004.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

*Contact Person:* Valerie L Prenger, PhD, MPH, Scientific Review Administrator, Review Branch, Room 7194, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, MSC 7924, Bethesda, MD 20892-7924, (301) 435-0288.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: December 8, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03-30816 Filed 12-11-03; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Aging Special Emphasis Panel, RD2 Success.

*Date:* December 16, 2003.

*Time:* 9 a.m. to 12 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institute on Aging, Gateway Bldg., Room 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892.

*Contact Person:* Mary Nekola, PHD, Chief of the Scientific Review Office, National Institute on Aging, Gateway Building, Room 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814-9692, 301-496-9666.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS.)

Dated: December 8, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03-30814 Filed 12-11-03; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; Notice of Closed Meetings

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 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 grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Aging Special Emphasis Panel, Nursing Homes.

*Date:* January 15, 2004.

*Time:* 11 a.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, 2C212, Bethesda, MD 20814, (Telephone Conference Call).

*Contact Person:* Alicja L. Markowska, PhD, DSC, Health Scientist Administrator, Scientific Review Office, National Institute on Aging, National Institutes of Health, Room 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301-402-7703, [markowska@nia.nih.gov](mailto:markowska@nia.nih.gov).

*Name of Committee:* National Institute on Aging Special Emphasis Panel, Aging and Oxidative Damage.

*Date:* March 3, 2004.

*Time:* 11 a.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, 2C212, Bethesda, MD 20814, (Telephone Conference Call).

*Contact Person:* Alicja L. Markowska, PhD, DSC, Health Scientist Administrator, Scientific Review Office, National Institute on Aging, National Institutes of Health, Room 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301-402-7703, [markowska@nia.nih.gov](mailto:markowska@nia.nih.gov).

*Name of Committee:* National Institute on Aging Special Emphasis Panel, Calcium in Brain Aging

*Date:* March 4-5, 2004.

*Time:* 5 p.m. to 7 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:* Louise L. Hsu, PhD, The Bethesda Gateway Building, 7201 Wisconsin Avenue/Suite 2C212, Bethesda, MD 20892, 301-496-7705.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 8, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03-30815 Filed 12-11-03; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Library of Medicine; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of meetings of the Board of Regents of the National Library of Medicine.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

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:* Board of Regents of the National Library of Medicine, Extramural Programs Subcommittee.

*Date:* February 9, 2004.

*Closed:* 4 p.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Library of Medicine, Building 38A, HPCC B1N30, 8600 Rockville Pike, Bethesda, MD 20892.

*Contact Person:* Donald A.B. Lindberg, MD, Director, National Library of Medicine, National Institutes of Health, PHS, DHHS, Bldg 38, Room 2E17B, Bethesda, MD 20894.

*Name of Committee:* Board of Regents of the National Library of Medicine, Subcommittee on Outreach and Public Information.

*Date:* February 10, 2004.

*Closed:* 7:30 a.m. to 8:45 a.m.

*Agenda:* Outreach Activities for the National Library of Medicine.

*Place:* National Institutes of Health, Building 38, Conference Room B, 2nd Floor, 8600 Rockville Pike, Bethesda, MD 20892.

*Contact Person:* Donald A.B. Lindberg, MD, Director, National Library of Medicine, National Institutes of Health, PHS, DHHS, Bldg 38, Room 2E17B, Bethesda, MD 20894.

*Name of Committee:* Board of Regents of the National Library of Medicine.

*Date:* February 10-11, 2004.

*Opened:* February 10, 2004, 9 a.m. to 4:30 p.m.

*Agenda:* Administrative Reports and Program Discussion.

*Place:* National Library of Medicine, Building 38, Board Room, 2nd Floor, 8600 Rockville Pike, Bethesda, MD 20892.

*Closed:* February 10, 2004, 4:30 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Library of Medicine, Building 38, Board Room, 2nd Floor, 8600 Rockville Pike, Bethesda, MD 20892.

*Opened:* February 11, 2004, 9 a.m. to 12 p.m.

*Agenda:* Administrative Reports and Program Discussion.

*Place:* National Library of Medicine, Building 38, Board Room, 2nd Floor, 8600 Rockville Pike, Bethesda, MD 20892.

*Contact Person:* Donald A.B. Lindberg, MD, Director, National Library of Medicine, National Institutes of Health, PHS, DHHS, Bldg 38, Room 2E17B, Bethesda, MD 20894.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.