

have inhalational exposure to *Bacillus anthracis*.

### C. Labeling

We encourage the submission of labeling supplements for penicillin G procaine injectable drug products. The revised labeling should contain a specific indication for inhalational anthrax (post-exposure), the recommended dosing regimen, safety information relevant to prolonged use and use in children, and other information described below. The following specific changes to the current approved labeling are recommended:

- **Indications.** In the "Indications" section, the indication for anthrax should be revised from "Anthrax" to "Anthrax due to *Bacillus anthracis*, including inhalational anthrax (post-exposure): to reduce the incidence or progression of the disease following exposure to aerosolized *Bacillus anthracis*."

- **Precautions.** In the "Precautions" section, at the end of the paragraph that begins "In prolonged therapy with penicillin, and particularly with high-dosage schedules, periodic evaluation of the renal and hematopoietic systems is recommended," the following text should be added: "In such situations, use of penicillin for more than 2 weeks may be associated with an increased risk of neutropenia and an increased incidence of serum sickness-like reactions."

- **Dosage and Administration.** In the "Dosage and Administration" section, immediately following "Anthrax—cutaneous: 600,000 to 1,000,000 units/day," the following text should be inserted:

"Anthrax—inhalational (post-exposure): 1,200,000 units every 12 hours in adults, 25,000 units per kilogram of body weight (maximum 1,200,000 unit) every 12 hours in children. The available safety data for penicillin G procaine at this dose would best support a duration of therapy of 2 weeks or less. Treatment for inhalational anthrax (post-exposure) must be continued for a total of 60 days. Physicians must consider the risks and benefits of continuing administration of penicillin G procaine for more than 2 weeks or switching to an effective alternative treatment."

### V. Conclusions

Drug products containing the following active ingredients are currently approved for administration in cases of inhalational anthrax:

- Doxycycline
- Doxycycline calcium
- Doxycycline hyclate
- Penicillin G procaine

We encourage the submission of labeling supplements for these drug

products. The revised labeling should specifically mention inhalational anthrax (post-exposure), the recommended dosing regimen, safety information relevant to prolonged exposure (60 days or longer), and other information described in this notice. The requirement for data to support these labeling changes may be met by citing the published literature we relied on in publishing this notice. A list of the published literature and reprints of the reports will be available for public inspection in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is unnecessary to submit copies and reprints of the reports from the listed published literature. We invite applicants to submit any other pertinent studies and literature of which they are aware.

### VI. Published Literature

The published literature we have relied on in making our recommendations will be placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. A list of this published literature will be on display in the Dockets Management Branch and on the Internet at [www.fda.gov/cder/drug/infopage/penG\\_doxy/bibliolist.htm](http://www.fda.gov/cder/drug/infopage/penG_doxy/bibliolist.htm).

Dated: October 26, 2001.

**Bernard A. Schwetz,**

*Acting Principal Deputy Commissioner.*

[FR Doc. 01-27493 Filed 10-29-01; 4:35 pm]

**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(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Advisory Committee to the Director, National Cancer Institute.

The meeting will be open to the public, 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.

*Name of Committee:* Advisory Committee to the Director, National Cancer Institute.

*Date:* November 20, 2001.

*Time:* 11 am to 1 pm.

*Agenda:* The purpose of the meeting will be to discuss the Gynecologic Cancers Progress Review, Group Report.

*Place:* National Cancer Institute, National Institutes of Health, 9000 Rockville Pike, Building 31, Room 11A03, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Chitra Mohla, Executive Secretary, Office of Scientific Opportunities, National Cancer Institute, National Institutes of Health, Bldg. 31, Rm. 11A03, Bethesda, MD 20892, (301) 496-1458.

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

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 homepage: [deainfo.nci.nih.gov/advisory/joint/htm](http://deainfo.nci.nih.gov/advisory/joint/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: October 26, 2001.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 01-27505 Filed 11-1-01; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Cancer Institute Director's Consumer Liaison Group.

The meeting will be open to the public, 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.

*Name of Committee:* National Cancer Institute Director's Consumer Liaison Group.

*Date:* November 8, 2001.

*Time:* 2 pm to 4 pm.

**Agenda:** To follow up on the Survivorship Forum and to get reports from the Working Groups.

**Place:** 6116 Executive Boulevard, Suite 300C, Rockville, MD 20852 (Telephone Conference Call).

**Contact Person:** Elaine Lee, Acting Executive Secretary, Office of Liaison Activities, National Institutes of Health, National Cancer Institute, 6116 Executive Boulevard, Suite 300 C, Bethesda, MD 20892, 301/594-3194.

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

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 homepage: [deainfo.nci.nih.gov/advisory/dclg/delg.htm](http://deainfo.nci.nih.gov/advisory/dclg/delg.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: October 26, 2001.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 01-27506 Filed 11-1-01; 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, Comparative Medicine.

**Date:** November 5, 2001.

**Time:** 10 am to Adjournment.

**Agenda:** To review and evaluate grant applications.

**Place:** Office of Review, National Center for Research Resources, 6705 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

**Contact Person:** Camille M. King, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, One Rockledge Centre, MSC 7965, 6705 Rockledge Drive, Suite 6018, Bethesda, MD 20892-7965, (301) 435-0810, [kingc@ncrr.nih.gov](mailto:kingc@ncrr.nih.gov).

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

Dated: October 24, 2001.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 01-27500 Filed 11-1-01; 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 Meeting

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

The meeting will be open to the public, 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.

**Name of Committee:** Sickle Cell Disease Advisory Committee.

**Date:** November 5, 2001.

**Time:** 8:30 AM to 5 PM.

**Agenda:** Discussion of Program policies and issues.

**Place:** National Institutes of Health, Two Rockledge Center, Conference Room 9112, 9116, 6701 Rockledge Drive, Bethesda, MD 20892.

**Contact Person:** Charles M Peterson, MD, Director, Blood Diseases Program, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, NIH, Two Rockledge Center, Room 10158, MSC 7950, 6701 Rockledge Drive, Bethesda, MD 20892, 301/435-0050.

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

Information is also available on the Institute's/Center's homepage: [www.nhlbi.nih.gov/meetings/index.htm](http://www.nhlbi.nih.gov/meetings/index.htm), where an agenda and any additional information for the meeting will be posted when available.

(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: October 24, 2001.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 01-27497 Filed 11-1-01; 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 a meeting of the Board of Scientific Counselors, NHLBI.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Heart, Lung, and Blood Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** Board of Scientific Counselors, NHLBI.

**Date:** December 13-14, 2001.

**Time:** 8 AM to 5 PM.

**Agenda:** To review and evaluate personal qualifications and performance, and competence of individual investigators.

**Place:** National Institutes of Health, 9000 Rockville, Pike, Building 10, Room 7S235, Bethesda, MD 20892.

**Contact Person:** Elizabeth G. Nabel, MD, Scientific Director for Clinical Research, National Heart, Lung, and Blood Institute, Division of Intramural Research, Building 10, Room 8C103, MSC 1754, Bethesda, MD 20892, 301/496-1518.

Information is also available on the Institute's/Center's homepage: [www.nhlbi.nih.gov/meetings/index.htm](http://www.nhlbi.nih.gov/meetings/index.htm),