rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product, ERAXIS (anidulafungin). ERAXIS is indicated for treatment of the following fungal infections: Candidemia and other forms of Candida infections (intra-abdominal abscess and peritonitis), and esophageal candidiasis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ERAXIS (U.S. Patent No. 5,965,525) from Eli Lilly and Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 6, 2007, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ERAXIS represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ERAXIS is 3,476 days. Of this time, 2,446 days occurred during the testing phase of the regulatory review period, while 1,030 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: August 14, 1996. The applicant claims July 15, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 14, 1996, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: April 25, 2003. The applicant claims August 18, 2005, as the date the new drug application (NDA) 21–948 for ERAXIS was initially submitted. However, FDA records indicate that NDA 21–948 was not the first NDA for anidulafungin submitted to the agency by Vicuron Pharmaceuticals, Inc., the owner of the applications at the time of submission. NDA 21–632, Vicuron's first NDA for anidulafungin, was submitted on April 25, 2003.

3. *The date the application was approved*: February 17, 2006. FDA has verified the applicant's claim that NDA 21–948 was approved on February 17, 2006. NDA 21–632 was also approved on February 17, 2006.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,224 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by August 22, 2008. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 22, 2008. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: June 9, 2008.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

[FR Doc. E8–14156 Filed 6–20–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of General Medical Sciences; 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:* Minority Programs Review Committee; Minority Programs Review Subcommittee A.

*Date:* July 10, 2008.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Westin Embassy Row Hotel, 2100 Massachusetts Avenue, NW., Washington, DC 20008.

*Contact Person:* Mona R. Trempe, PhD, Scientific Review Officer, Office of Scientific

Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, MD 20892, 301–594–3998, *trempemo@mail.nih.gov*.

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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: June 17, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8–14139 Filed 6–20–08; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of General Medical Sciences; 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 the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel; Bridges to Baccalaureate.

*Date:* July 15, 2008

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

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

*Contact Person:* Helen R. Sunshine, PhD, Chief, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN–12F, Bethesda, MD 20892, 301–594–2881, *sunshinh@nigms.nih.gov*.

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.

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel; Training Grants.

*Date:* July 15, 2008.

*Time:* 1 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Building 45, Room 3AN18F, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Arthur L. Zachary, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN–12, Bethesda, MD 20892, (301) 594–2886, *zacharya@nigms.nih.gov*.

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.

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel; Trauma and Burn.

*Date:* July 18, 2008.

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

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Lisa Dunbar, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, MD 20892, 301–594–2849, *dunbarl@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: June 17, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8–14138 Filed 6–20–08; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[Docket # USCG–2008–0369]**

### Area Maritime Security Advisory Committee (AMSC), Boston, MA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Solicitation for Membership.

**SUMMARY:** This notice requests individuals interested in serving on the Area Maritime Security Committee (AMSC) Boston, MA submit their applications for membership to the Captain of the Port (COTP) Boston, MA.

**DATES:** Requests for membership should reach the U.S. Coast Guard Captain of the Port Boston, MA by July 23, 2008.

**ADDRESSES:** Applications for membership should be submitted to the Captain of the Port at the following address: Captain of the Port Boston, U.S. Coast Guard Sector Boston, Contingency Planning and Force Readiness Department, 427 Commercial St., Boston, MA 02109.

**FOR FURTHER INFORMATION CONTACT:** For questions about submitting an application or about the AMSC in general, contact Mr. Phillip Smith, 617–223–3008.

**SUPPLEMENTARY INFORMATION:**

#### Authority

Section 102 of the Maritime Transportation Security Act (MTSA) of 2002 (Pub. L. 107–295) added section 70112 to Title 46 of the U.S. Code, and authorized the Secretary of the Department in which the Coast Guard is operating to establish Area Maritime Security Advisory Committees for any port area of the United States. (See 33 U.S.C. 1226; 46 U.S.C.; 33 CFR 1.05–1, 6.01; Department of Homeland Security Delegation No. 0170.1). The MTSA includes a provision exempting these AMSCs from the Federal Advisory Committee Act (FACA), Public Law 92–436, 86 Stat. 470 (5 U.S.C. App. 2). The AMSCs shall assist the Captain of the Port in the development, review, update, and exercising of the AMS Plan for their area of responsibility. Such matters may include, but are not limited to: identifying critical port infrastructure and operations; identifying risks (threats, vulnerabilities, and consequences); determining mitigation strategies and implementation methods; developing strategies to facilitate the recovery of the MTS after a Transportation Security Incident; developing and describing the process to continually evaluate overall port security by considering consequences and vulnerabilities, how they may change over time, and what additional mitigation strategies can be applied; and providing advice to, and assisting the Captain of the Port in developing and maintaining the Area Maritime Security Plan.

#### AMSC Membership

Members of the AMSC should have at least 5 years of experience related to maritime or port security operations. The Boston AMSC has 29 members. We are seeking to fill 6 vacancies with this solicitation. Applicants may be required to pass an appropriate security background check prior to appointment