

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: January 16, 2002.

**Bob Sargis,**

*Reports Clearance Officer.*

[FR Doc. 02-1634 Filed 1-22-02; 8:45 am]

BILLING CODE 4184-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Vaccines and Related Biological Products Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on January 30, 2002, from 9 a.m. to 5 p.m.

*Location:* Holiday Inn, Versailles I and II, 8120 Wisconsin Ave., Bethesda, MD.

*Contact:* William Freas or Denise H. Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On January 30, 2002, the committee will discuss the influenza virus vaccine formulation for the 2002-2003 season.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 22, 2002. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 9:45 a.m., and approximately 4:15 p.m. and 5 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 22, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the Vaccines and Related Biological Products Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Vaccines and Related Biological Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 17, 2001.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

[FR Doc. 02-1713 Filed 1-18-02; 1:52 pm]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing; Methods for Preparing Bacillus Anthracis Protective Antigen for Use in Vaccines

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** The invention described below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by contacting Peter A. Soukas, J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7056 ext. 268; fax: 301/402-0220; e-mail: [soukasp@od.nih.gov](mailto:soukasp@od.nih.gov). A signed Confidential Disclosure Agreement will be required to receive a copy of the patent application.

#### Methods for Preparing *Bacillus Anthracis* Protective Antigen for Use in Vaccines

Joseph Shiloach (NIDDK), Stephen Leppla (NIDCR), Delia Ramirez (NIDDK), Rachel Schneerson (NICHHD), John Robbins (NICHHD) DHHS Reference No. E-023-02/0 filed 09 Nov 2001

This invention relates to improved methods of preparing *Bacillus anthracis* protective antigen (PA) for use in vaccines. PA is a secreted, non-toxic protein with a molecular weight of 83 KDa. PA is a major component of the currently licensed human vaccine (Anthrax Vaccine Adsorbed, AVA). Although the licensed human vaccine has been shown to be effective against cutaneous anthrax infection in animals and humans and against inhalation anthrax in rhesus monkeys, the licensed vaccine has several limitations: (1) AVA elicits a relatively high degree of local and systemic adverse reactions, probably mediated by variable amounts of undefined bacterial products, making standardization difficult; (2) the immunization schedule requires

administration of six doses within an eighteen (18) month period, followed by annual boosters; (3) there is no defined vaccine-induced protective level of antibody to PA by which to evaluate new lots of vaccines; and (4) AVA is comprised of a wild-type PA. It has been suggested that a vaccine comprising a modified purified recombinant PA would be effective, safe, allow precise standardization, and require fewer injections.

This invention claims methods of producing and recovering PA from a cell or organism, particularly a recombinant cell or microorganism. The invention claims production and purification of modified PA from a non-sporogenic strain of *Bacillus anthracis*. In contrast to other previously described methods, greater quantities of PA are obtainable from these cells or microorganisms. Specifically, a scalable fermentation and purification process is claimed that is suitable for vaccine development, and that produces almost three times more product than earlier-reported processes. This is accomplished using a biologically inactive protease-resistant PA variant in a protease-deficient non-sporogenic avirulent strain of *B. anthracis* (BH445). One of the PA variants described in the patent application lacks the furin and chymotrypsin cleavage sites.

The invention also relates to PA variants, and/or compositions thereof, which are useful for eliciting an immunogenic response in mammals, particularly humans, including responses that provide protection against, or reduce the severity of, infections caused by *B. anthracis*. The vaccines claimed in this application are intended for active immunization for prevention of *B. anthracis* infection, and for preparation of immune antibodies.

Dated: January 15, 2002.

**Jack Spiegel,**

*Director, Division of Technology, Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. 02-1613 Filed 1-22-02; 8:45 am]

**BILLING CODE 4140-01-P**

## 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:* National Heart, Lung, and Blood Institute Special Emphasis Panel Mentored Scientist Development Award.

*Date:* February 18-19, 2002.

*Time:* 7:00 PM to 4:30 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn—Chevy Chase, 5520 Wisconsin Avenue, Bethesda, MD 20815.

*Contact Person:* Roy L. White, PhD, Review Branch, NIH, NHLBI, Rockledge Building II, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892, 301-435-0291.

(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: January 16, 2002.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 02-1608 Filed 1-22-02; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Neurological Disorders and Stroke; 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 Neurological Disorders and Stroke Initial Review Group Neurological Sciences and Disorders K.

*Date:* February 10-11, 2002.

*Time:* 8:30 AM to 5:00 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* Hawthorne Suites, Riverwalk, 830 N. St. Mary's, San Antonio, TX 78205.

*Contact Person:* Katherine M. Woodbury, PhD, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd, Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Initial Review Group Neurological Sciences and Disorders A.

*Date:* February 10-11, 2002.

*Time:* 8:30 AM to 5:00 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* Hawthorne Suites, Riverwalk, 830 N. St. Mary's, San Antonio, TX 78205.

*Contact Person:* Richard D. Crosland, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd, Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Initial Review Group Neurological Sciences and Disorders C.

*Date:* February 25-26, 2002.

*Time:* 8:00 AM to 5:00 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* Radisson Barcelo Hotel, 2121 P St., NW, Washington, DC 20037.

*Contact Person:* Alan L. Willard, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Initial Review Group Neurological Sciences and Disorders B.

*Date:* February 25-26, 2002.

*Time:* 8:30 AM to 6:00 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* Radisson Barcelo Hotel, 2121 P St., NW, Washington, DC 20037.

*Contact Person:* W. Ernest Lyons, PhD, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-4056.

*Name of Committee:* Training Grant and Career Development Review Committee.

*Date:* February 28-March 1, 2002.

*Time:* 8:00 AM to 5:00 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* Westin Grand Hotel, 2350 M Street, NW, Washington, DC 20037-1417.

*Contact Person:* Raul A. Saavedra, PhD, Scientific Review Administrator, Scientific