Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from April 1, 2008, through June 30, 2008. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM APRIL 1, 2008, THROUGH JUNE 30, 2008

| PMA No./Docket No. | Applicant | TRADE NAME | Approval Date |
|---|---|---|---|
| P050020<br>FDA–2008–M–0207 | Abbott Diabetes Care, Inc. | FREESTYLE NAVIGATOR CONTINUOUS GLUCOSE MONITORING SYSTEM | March 12, 2008 |
| P010012 (S037)<br>FDA–2008–M–0243 | Guidant Corp. | Contak Renewal 3 AVT system & contak reviewal 3AVT HE System | March 13, 2008 |
| P070027<br>FDA–2008–M–0244 | Medtronic Vascular | The talent abdominal stent graft system | April 15, 2008 |
| P060040<br>FDA–2008–M–0283 | Thoratec Corp. | Thoratec Heartmate II Left ventricular assist | April 21, 2008 |
| P070008<br>FDA–2008–M–0335 | Biotronik, Inc. | Stratos LV CRT–P & stratos LV–T CRT–P, corox OTW BP lead & corox OTW-s bp lead | May 12, 2008 |
| P070016<br>FDA–2008–M–0311 | Cook, Inc. | Zenith TX2 Thoracic TAA endovascular graft with the H&LB One-shot introduction system | May 21, 2008 |
| P070007<br>FDA–2008–M–0342 | Medtronic Vascular | Talent Thoracic Stent Graft System | June 5, 2008 |
| H070003<br>FDA–2008–M–0378 | Synapse Biomedical, Inc. | NeuRx RA/4 | June 17, 2008 |

## II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html*.

Dated: September 12, 2008.

**Daniel G. Schultz,**

*Director, Center for Devices and Radiological Health.*

[FR Doc. E8–22668 Filed 9–25–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

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

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are 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 writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

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

*Description of Technology:* This invention relates to improved methods of preparing *Bacillus anthracis* protective antigen (PA) from a cell or organism, particularly a recombinant cell or microorganism, for use in vaccines. Production and purification methods of modified PA from a non-sporogenic strain of *Bacillus anthracis* are described. 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.

*Advantages: Bacillus anthracis* protective antigen is a major component of the currently licensed human vaccine (Anthrax Vaccine Adsorbed, AVA). Although the current 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. Thus a vaccine comprising a modified purified recombinant PA would be effective, safe, allow precise standardization, and require fewer injections.

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.

*Application:* Improved *B. anthracis* vaccines.

*Development Status:* Phase I clinical studies are being performed.

*Inventors:* Joseph Shiloach (NIDDK), Stephen Leppla (NIDCR), Delia Ramirez (NIDDK), Rachel Schneerson (NICHD), John Robbins (NICHD).

*Publication:* DM Ramirez *et al.* Production, recovery and immunogenicity of the protective antigen from a recombinant strain of *Bacillus anthracis*. J Ind Microbiol Biotechnol. 2002 Apr;28(4):232–238.

*Patent Status:* U.S. Patent Application No. 10/290,712 filed 08 Nov 2002 (HHS Reference No. E–023–2002/0–US–02)

*Licensing Status:* Available for exclusive or nonexclusive licensing.

*Licensing Contact:* Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*.

*Collaborative Research Opportunity:* The National Institutes of Health is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize methods of preparing *Bacillus anthracis* protective antigen (PA) from a cell or organism, particularly a recombinant cell or microorganism, for use in vaccines. Please contact Rochelle S. Blaustein, J.D., at 301/451–3636 or *Rochelle.Blaustein@nih.gov* for additional information.

**Recombinant Modified *Bacillus anthracis* Protective Antigen for Use in Vaccines**

*Description of Technology:* 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 relates to improved methods of producing and recovering sporulation-deficient *B. anthracis* mutant stains, and for producing and recovering recombinant *B. anthracis* protective antigen (PA), especially modified PA which is protease resistant, and to methods of using of these PAs or nucleic acids encoding these PAs for eliciting an immunogenic response in humans, including responses which provide protection against, or reduce the severity of, *B. anthracis* bacterial infections and which are useful to prevent and/or treat illnesses caused by *B. anthracis*, such as inhalation anthrax, cutaneous anthrax and gastrointestinal anthrax.

*Application:* Improved *B. anthracis* vaccines.

*Development Status:* Phase I clinical studies are being performed.

*Inventors:* Stephen Leppla (NIDCR), M. J. Rosovitz (NIDCR), John Robbins (NICHD), Rachel Schneerson (NICHD).

*Patent Status:* U.S. Patent No. 7,261,900 issued 28 Aug 2007 (HHS Reference No. E–268–2002/0–US–02); U.S. Patent Application No. 11/831,860 filed 31 Jul 2007 (HHS Reference No. E–268–2002/0–US–03).

*Licensing Status:* Available for exclusive or nonexclusive licensing.

*Licensing Contact:* Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*.

**γPGA Conjugates for Eliciting Immune Responses Directed Against *Bacillus anthracis* and Other Bacilli**

*Description of Technology:* This invention claims immunogenic conjugates of a poly-γ-glutamic acid (γPGA) of *B. anthracis*, or of another bacillus that expresses a γPGA that elicit a serum antibody response against *B. anthracis*, in mammalian hosts to which the conjugates are administered. The invention also relates methods which are useful for eliciting an immunogenic response in mammals, particularly humans, including responses which 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. The vaccines of this invention are designed to confer specific immunity against infection with *B. anthracis*, and to induce antibodies specific to *B. anthracis* γPGA. The *B. anthracis* vaccine is composed of non-toxic bacterial components, suitable for infants, children of all ages, and adults.

*Inventors:* Rachel Schneerson (NICHD), Stephen Leppla (NIAID), John Robbins (NICHD), Joseph Shiloach (NIDDK), Joanna Kubler-Kielb (NICHD), Darrell Liu (NIDCR), Fathy Majadly (NICHD).

*Publication:* R Schneerson et al. Poly(gamma-D-glutamic acid) protein conjugates induce IgG antibodies in mice to the capsule of *Bacillus anthracis*: a potential addition to the

anthrax vaccine. Proc Natl Acad Sci USA. 2003 Jul 22;100(15):8945–8950.

*Patent Status:* U.S. Patent Application No. 10/559,825 filed 02 Dec 2005, claiming priority to 05 Jun 2003 (HHS Reference No. E–343–2002/0–US–04).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*.

**Improved Bacterial Host for Production of Anthrax Toxin Proteins and Vaccines: *Bacillus anthracis* BH450**

*Description of Invention:* Anthrax toxin has previously been made from various avirulent strains of *Bacillus anthracis*. The inventors have genetically engineered a new strain of *B. anthracis* with improved properties. The strain, designated BH450, is totally deficient in the ability to make spores and to produce a major extracellular protease designated Peptidase M4. The genetic lesions introduced are defined, true deletions, so there is no possibility of reversion. Inability to make spores assures that laboratories growing the strain will not become contaminated with the very stable anthrax spores. Inability to make peptidase M4 increases the stability of proteins such as anthrax toxin that are secreted to the culture medium.

*Applications and Modality: B. anthracis* vaccine/prophylactic and therapeutic studies.

*Market:* Research tool useful for biodefense/therapeutic studies.

*Development Status:* The technology is a research tool.

*Inventors:* Andrei Pomerantsev, Dana Hsu, Ramakrishnan Sitaraman, Craig Galloway, Violetta Kivovich, Stephen Leppla (NIAID).

*Publication:* AP Pomerantsev *et al.* Genome engineering in Bacillus anthracis using Cre recombinase. Infect Immun. 2006 Jan;74(1):682–693.

*Patent Status:* HHS Reference No. E–127–2007/0—Research Tool.

*Licensing Status:* This technology is not patented. The strain will be transferred through a Biological Materials License.

*Licensing Contact:* Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*.

*Collaborative Research Opportunity:* The National Institute of Allergy and Infectious Diseases, Laboratory of Bacterial Diseases, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize *Bacillus anthracis* BH450 strain. Please contact Dr. Andrei P. Pomerantsev at phone 301/451–9817 and/or e-mail *apomerantsev@niaid.nih.gov* for more information.

**Monoclonal Antibodies That Neutralize *B. anthracis* Protective Antigen (PA), Lethal Factor (LF) and Edema Factor (EF)**

*Description of Invention:* Anthrax, whether resulting from natural or bioterrorist-associated exposure, is a constant threat to human health. The lethality of anthrax is primarily the result of the effects of anthrax toxin, which has 3 components: a receptor-binding protein known as ''protective antigen'' (PA) and 2 catalytic proteins known as ''lethal factor'' (LF) and ''edema factor'' (EF). Although production of an efficient anthrax vaccine is an ultimate goal, the benefits of vaccination can be expected only if a large proportion of the population at risk is immunized. The low incidence of anthrax suggests that large-scale vaccination may not be the most efficient means of controlling this disease. In contrast, passive administration of neutralizing human or chimpanzee monoclonal antibody to a subject at risk for anthrax or exposed to anthrax could provide immediate efficacy for emergency prophylaxis against or treatment of anthrax.

Four monoclonal antibodies (mAbs) against PA, three mAbs against LF and four mAbs specific for EF of anthrax were isolated from a phage display library generated from immunized chimpanzees. Two mAbs recognizing PA (W1 and W2), two anti-LF mAbs efficiently neutralized the cytotoxicity of lethal toxin in a macrophage lysis assay. One anti-EF mAb efficiently neutralized edema toxin in cell culture. All five neutralizing mAbs protected animals from anthrax toxin challenge.

*Application:* Prophylactics or therapeutics against *B. anthracis*.

*Developmental Status:* Preclinical studies have been performed.

*Inventors:* Zhaochun Chen, Robert Purcell, Suzanne Emerson, Stephen Leppla, Mahtab Moyeri (NIAID).

*Publication:* Z Chen *et al.* Efficient neutralization of anthrax toxin by chimpanzee monoclonal antibodies against protective antigen. J Infect Dis. 2006 Mar 1;193(5):625–633.

*Patent Status:* PCT Application No. PCT/US2008/054609 filed 21 Feb 2008, claiming priority to 23 Feb 2007 (HHS Reference No. E–123–2007/0–PCT–02); U.S. Patent Application No. 11/793,735 filed 22 Jun 2007 (HHS Reference No. E–146–2004/0–US–03)

*Licensing Status:* Available for exclusive or non-exclusive licensing.

*Licensing Contact:* Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*.

*Collaborative Research Opportunity:* The National Institute of Allergy and Infectious Diseases, Laboratory of Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Chimpanzee/human neutralizing monoclonal antibodies against anthrax toxins. Please contact Dr. Robert Purcell at 301/496–5090 for more information.

Dated: September 18, 2008.

**Richard U. Rodriguez,**

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

[FR Doc. E8–22608 Filed 9–25–08; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

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

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are 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.

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**Inhibitors of the Plasmodial Surface Anion Channel as Antimalarials**

*Description of Technology:* The inventions described herein are antimalarial small molecule inhibitors of the plasmodial surface anion channel (PSAC), an essential nutrient acquisition ion channel expressed on human