with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 017. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: May 10, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–9718 Filed 5–18–07; 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.

A Method With Increased Yield for Production of Polysaccharide-Protein Conjugate Vaccines Using Hydrazide Chemistry

Description of Technology: Current methods for synthesis and manufacturing of polysaccharide-protein conjugate vaccines employ conjugation reactions with low efficiency (about twenty percent). This means that up to eighty percent of the added activated polysaccharide (PS) is lost. In addition, inclusion of a chromatographic process for purification of the conjugates from unconjugated PS is required.

The present invention utilizes the characteristic chemical property of hydrazide groups on one reactant to react with aldehyde groups or cyanate esters on the other reactant with an improved conjugate yield of at least sixty percent. With this conjugation efficiency the leftover unconjugated protein and polysaccharide would not need to be removed and thus the purification process of the conjugate product can be limited to diafiltration to remove the by-products of small molecules. The new conjugation reaction can be carried out within one or two days with reactant concentrations between 1 and 25 mg/mL at PS/protein ratios from 1:2 to 3:1, at temperatures between 4 and 40 degrees Centigrade, and in a pH range of 5.5 to 7.4, optimal conditions varying from PS to PS.

Application: Cost effective and efficient manufacturing of conjugate vaccines.

Inventors: Che-Hung Robert Lee and Carl E. Frasch (CBER/FDA).

Patent Status: U.S. Patent Application No. 10/566,899 filed 01 Feb 2006, claiming priority to 06 Aug 2003 (HHS Reference No. E–301–2003/0–US–10); U.S. Patent Application No. 10/566,898 filed 01 Feb 2006, claiming priority to 06 Aug 2003 (HHS Reference No. E–301–2003/1–US–02); International rights available.

Licensing Status: Available for non-exclusive licensing.

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

A Method of Immunizing Humans Against Salmonella Typhi Using a Vi-rEPA Conjugate Vaccine

Description of Technology: This invention is a method of immunization against typhoid fever using a conjugate vaccine comprising the capsular polysaccharide of *Salmonella typhi*, Vi, conjugated through an adipic dihydrazide linker to nontoxic recombinant exoprotein A (rEPA) from *Pseudomonas aeruginosa*. The three licensed vaccines against typhoid fever, attenuated *S. typhi* Ty21a, killed whole cell vaccines and Vi polysaccharide, have limited efficacy, in particular for children under 5 years of age, which make an improved vaccine desirable.

It is generally recognized that an effective vaccine against *Salmonella typhi* is one that increases serum anti-Vi IgG eight-fold six weeks after immunization. The conjugate vaccine of the invention increases anti-Vi IgG, 48-fold, 252-fold and 400-fold in adults, in 5–14 years-old and 2–4 years-old children, respectively. Thus this is a highly effective vaccine suitable for children and should find utility in endemic regions and as a traveler's vaccine. The route of administration can also be combined with routine immunization. In 2–5 years old, the protection against typhoid fever is 90% for 4 years. In school age children and in adults the protection could mount to completer protection according to the immunogenicity data.

Application: Immunization against *Salmonella typhi* for long term prevention of typhoid fever in all ages.

Developmental Status: Conjugates have been synthesized and clinical studies have been performed. The synthesis of the conjugates is described by Kossaczka et al. in Infect Immun. 1997 June;65(7):2088–2093. Phase III clinical studies are described by Mai et al. in N Engl J Med. 2003 October 2; 349(14):1390–1391. Dosage studies are described by Canh et al. in Infect Immun. 2004 Nov;72(11):6586–6588.

A safety and immunogenicity study in infants are underway. The aim is to administer the conjugate vaccine with routine infant immunization. Preliminary results show the vaccine is safe in 2 months old infants.

Inventors: Zuzana Kossaczka, Shousun C. Szu, and John B. Robbins (NICHD).

Patent Status: U.S. Patent 6,797,275 issued 28 Sep 2004 (HHS Reference No. E–020–1999/0–US–02); U.S. Patent Application No. 10/866,343 filed 10 Jun 2004 (HHS Reference No. E–020–1999/0–US–03); U.S. Patent Application No. 11/726,304 filed 20 Mar 2007 (HHS Reference No. E–020–1999/0–US–04).

Licensing Status: Available for non-exclusive licensing.

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

Collaborative Research Opportunity: The National Institute of Child Health and Human Development, Laboratory of Developmental and Molecular Immunity, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize A Method of Immunizing Humans Against Salmonella Typhi Using a Vi-rEPA Conjugate Vaccine. Please contact John D. Hewes, Ph.D., at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Vaccine Against *Escherichia Coli* 0157 Infection, Composed of Detoxified LPS Conjugated to Proteins

Description of Technology: This invention is a conjugate vaccine to prevent infection by *E. coli* 0157:H7, particularly in young children under 5 years of age. *E. coli* 0157:H7 is an emerging human pathogen which causes a spectrum of illnesses with high morbidity and mortality, ranging from diarrhea to hemorrhagic colitis and hemolytic-uremic syndrome (HUS). Infection with *E. coli* 0157:H7 occurs as a result of consumption of water, vegetables, fruits or meat contaminated by feces from infected animals, such as cattle. The most recent large outbreak in the U.S. was from contaminated bag spinach. The conjugate is composed of the O-specific polysaccharide isolated from *E. coli* 0157, or other Shiga-toxin producing bacteria, conjugated to carrier proteins, such as non-toxic *P. aeruginosa* exotoxin A or Shiga toxin 1. A Phase I clinical trial, involving adult humans, showed the vaccine is safe and highly immunogenic. Adults, after one injection containing 25 μg of antigen, responded with high titers of bactericidal antibodies. Similarly in a phase II study, fifty 2-to-5- years old children in U.S. were injected with the conjugate vaccines. There were only mild local adverse reactions. More than 90% of the children responded with greater than 10 fold rise of *E. coli* O157 antibodies of bactericidal ability. Thus the conjugates of the invention are promising vaccines, especially for children and the elderly, who are most likely to suffer serious consequences from infection.

Application: Prevention of *E. coli* O157 infection.

Development Status: Clinical studies have been performed and are described in Konadu *et al.,* J Infect Dis. 1998 Feb; 177(2):383–387 and Ahmed *et al.,* J Infect Dis. 2006 Feb; 193(2):515–526.

Inventors: Shousun C. Szu, Edward Konadu, and John B. Robbins (NICHD).

Patent Status: U.S. Patent 6,858,211 issued 22 Feb 2005 (HHS Reference No. E–158–1998/0–US–06); U.S. Patent Application No. 10/987,428 filed 12 Nov 2004 (HHS Reference No. E–158–1998/0–US–07); U.S. Patent Application No. 11/015,436 filed 16 Dec 2004 (HHS Reference No. E–158–1998/0–US–08).

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

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

Collaborative Research Opportunity: The National Institute of Child Health and Human Development, Laboratory of Developmental and Molecular Immunity, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Vaccine for *E. coli* O157 for Children and Adults. Please contact John D. Hewes, Ph.D., at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: May 11, 2007.

Steven M. Ferguson,

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

[FR Doc. E7–9656 Filed 5–18–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, June 14, 2007, 2 p.m. to June 15, 2007, 12 p.m., National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892, which was published in the **Federal Register** on May 2, 2007, 72 FR 24319.

The notice is being amended to change the open session start and end times on June 14, 2007 to 1:15 p.m.—4:20 p.m. and the end time on June 15, 2007 to 11:45 a.m. The meeting is partially Closed to the public.

Dated: May 14, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–2495 Filed 5–18–07; 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 provision 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: June 25, 2007.

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

Agenda: To review and evaluate grant applications.

Place: Intercontinental Harbor Court, 550 Light Street, Baltimore, MD 21202.

Contact Person: Patricia A Haggerty, PhD, Section Chief, Clinical Studies and Training Scientific Review Group, Review Branch, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, NIH, 6701 Rockledge Drive, Room 7194, MSC 7924, Bethesda, MD 20892, 301/435–0288, *haggertp@nhlbi.nih.gov.*

(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: May 14, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–2488 Filed 5–18–07; 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 give 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 Award (K99).

Date: June 28–29, 2007.

Time: June 28, 2007, 12 p.m. to 10 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza, 10 Thomas Circle NW., Washington, DC 20005.