approximately 214,400 registered users of the PN System Interface will submit an average of 8.33 prior notices annually, for a total of 1,785,952 prior notices received annually through the PN System Interface. FDA estimates the reporting burden for a prior notice submitted through the PN System Interface to be 23 minutes, or 0.384 hours, per notice, for a total burden of 685,806 hours.

FDA received no cancellations of prior notices through ABI/ACS during December 2003; 16,624 during 2004; and 21,720 during 2005. Based on this experience, FDA estimates that approximately 6,500 users of ABI/ACS will submit an average of 3.34 cancellations annually, for a total of 21,710 cancellations received annually through ABI/ACS. FDA estimates the reporting burden for a cancellation submitted through ABI/ACS to be 15 minutes, or 0.25 hours, per cancellation, for a total burden of 5,428 hours.

FDA received 1,539 cancellations of prior notices through the PN System Interface during December 2003; 64,918 during 2004; and 65,491 during 2005. Based on this experience, FDA estimates that approximately 214,400 registered users of the PN System Interface will submit an average of 0.31 cancellations annually, for a total of 66,464 cancellations received annually through the PN System Interface. FDA estimates the reporting burden for a cancellation submitted through the PN System Interface to be 15 minutes, or 0.25 hours, per cancellation, for a total burden of 16,616 hours.

FDA has not received any requests for review under §§ 1.283(d) or 1.285(j) in the last 3 years (December 2003 through 2005); therefore, the agency estimates no more than one request for review will be submitted annually. FDA estimates that it will take a requestor about 8 hours to prepare the factual and legal information necessary to prepare a request for review. Thus, FDA has estimated a total reporting burden of 8 hours.

FDA has not received any post-hold submissions under § 1.285(i) in the last 3 years (December 2003 through 2005); therefore, the agency estimates no more than one post-hold submission will be submitted annually. FDA estimates that it will take about 1 hour to prepare the written notification described in § 1.285(i)(2)(i). Thus, FDA has estimated a total reporting burden of 1 hour.

In cases where a regulation implements a statutory information collection requirement, only the additional burden attributable to the regulation, if any, has been included in FDA's burden estimate.

Dated: December 13, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–21737 Filed 12–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0478]

Marketed Unapproved Drugs; Public Workshop; Change of Meeting Location and Time

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a change of location and time for the upcoming public workshop on marketed unapproved drugs. Registration for the public workshop is closed. A new address and time are given for those persons who have previously registered with FDA.

DATES: The public workshop will be held on January 9, 2007, from 8:30 a.m. to 4:30 p.m.

ADDRESSES: The public workshop will be held in the Universities at Shady Grove, Conference Center Auditorium, bldg. 1, 9640 Gudelsky Dr., Rockville, MD. Directions and information on parking, hotels, and transportation options can be found at *http://www.shadygrove.umd.edu/conference*. The agenda for the workshop will be posted at *http://www.fda.gov/cder/drug/unapproved_drugs*.

FOR FURTHER INFORMATION CONTACT: Karen Kirchberg, Center for Drug Evaluation and Research (HFD–330), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–8916, e-mail: *Karen.Kirchberg@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 1, 2006 (71 FR 64284), FDA issued a notice announcing a public workshop on issues related to the application process for seeking approval for marketed unapproved drugs. The November 1, 2006, notice invited individuals interested in attending the workshop to register and submit topics for discussion by November 15, 2006. Registration for the workshop is closed. Attendance at the workshop is limited to those persons who have previously registered with FDA.

Because of a greater than anticipated response for attending the public workshop, FDA is announcing in this notice a new location and time.

II. New Location and Time for the Public Workshop

The new location will be the Universities at Shady Grove, Conference Center Auditorium (see **ADDRESSES**). Directions and information on parking, hotels, and transportation options can be found at *http://www.shadygrove.umd.edu/conference*. The new time will be 8:30 a.m. to 4:30 p.m.

Dated: December 14, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–21738 Filed 12–19–06; 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.

Production, Recovery and Purification Process for Plasmid DNA Clinical Manufacturing

Description of Technology: Available for licensing from NIH is a method for large scale production, recovery, and purification process for plasmid DNA manufacturing meeting human clinical trial requirements. DNA plasmid

recovery and purification methods can separate plasmid from contamination from a variety of sources including cellular debris and proteins as well as genomic DNA and RNA. Traditionally, DNA plasmid recovery methods utilizing column chromatography have had poor results such as product elutes with broad smears rather than sharp peaks, product elutes appearing in the flow through thereby preventing isolation from lysate components, and monomeric supercoiled plasmids are not separated from other forms of plasmids. To overcome these shortcomings, a fermentation, recovery, purification, and formulation process for the production of plasmid has been developed. The overall recovery of this process is greater than 400 mg of formulated final product per kilogram (wet weight) of E. coli cell paste.

Applications: (1) Produce clinical grade plasmid DNA for clinical trials; (2) Therapeutic reagents.

Market: This technology has potential uses in drug manufacturing and clinical studies. In the United States alone, there were approximately over 40,000 clinical trials conducted. The potential market is worth several billion dollars.

Inventors: Yueqing Xie *et al.* (NCI/SAIC).

Related Publications:

1. N Horn *et al.* U.S. Patent No. 5,707,812, Purification of plasmid DNA during column chromatography.

2. R Lemmens *et al.* Supercoiled plasmid DNA: selective purification by thiophilic/aromatic adsorption. J Chromatogr B Analyt Technol Biomed Life Sci. 2003 Feb 5;784(2):291–300.

3. J Urthaler *et al.* Application of monoliths for plasmid DNA purification development and transfer to production. J Chromatogr A 2005 Feb 11;1065(1):93–106.

Patent Status: HHS Reference No. E–033–2007/0—Research Tool.

Licensing Status: This technology is available as a non-exclusive license.

Licensing Contact: Jennifer Wong; 301/435–4633; *wongje@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute—Frederick is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize A Production, Recovery and Purification Process for Plasmid DNA Clinical Manufacturing. Please contact Betty Tong, PhD at *tongb@mail.nih.gov* for more information.

Chitosan as a Universal Vaccine Adjuvant, Antigen Depot and Cytokine Depot

Description of Technology: This technology describes the use of chitosan depots with appropriate antigens and/or cytokines for generating an immune response in a subject. Such depots are made by mixing one or more antigens and/or cytokines with chitosan or a chitosan derivative. Similar compositions are described wherein chitosan or a derivative forms a micro- or nanoparticle, which have resulted in a more immunogenic presentation of antigen compared to antigen in solution. Using a representative antigen, the inventors showed that mice vaccinated with the subject depots had increased humoral and cellular immune responses compared to mice vaccinated with antigen alone.[1] Furthermore, comparative mouse studies showed the antigen-specific immune response generated with chitosan depots of this invention to be equipotent to incomplete Freund's adjuvant (IFA) and superior to aluminum hydroxide, a widely used adjuvant for licensed and routinely administered vaccines.[1] Thus, this technology improves upon commonly used adjuvant technology and is widely applicable. This technology is the first to show that subcutaneous administrations of chitosan and an appropriate antigen, with no other component, can be used for enhancing immune responses. In additional studies, the inventors showed that chitosan is able to maintain a depot of recombinant cytokine. A single subcutaneous injection of chitosan-cytokine outperforms daily injections of recombinant cytokine in both the expansion of draining lymph nodes and in the antigen presenting ability of lymph node cells. This technology is the first to show that chitosan can maintain a depot of cytokine which results in a significant enhancement of the functional effects of a cytokine. This technology can be used for vaccines and immunotherapies against various infectious agents and cancer.

Applications: Vaccine adjuvant; Immunogenic depots, including vaccine and cytokine.

Development Status: Animal (mouse) data available.

Inventor: Jeffrey Schlom *et al.* (NCI).

Reference: [1] DA Zaharoff, CJ Rogers, KW Hance, J Schlom, JW Greiner. Chitosan solution enhances both humoral and cell-mediated immune responses to subcutaneous vaccination. Vaccine (accepted November 2006).

Patent Status: U.S. Provisional Application No. 60/846,481 filed 22 Sep 2006 (HHS Reference No. E–311–2006/0–US–01).

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

Licensing Contact: Susan Ano, PhD; 301/435–5515; *anos@mail.nih.gov*

Collaborative Research Opportunity: The NCI Laboratory of Tumor Immunology and Biology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize chitosan-mediated immunopotentiation of vaccines and immunotherapies. Please contact Betty Tong, PhD at 301–594–4263 or *tongb@mail.nih.gov* for more information.

Preparative Two Dimensional Gel Electrophoresis System

Description of Technology: The National Institute of Environmental Health Sciences has developed procedures and a prototype device for isolation of proteins from complex mixtures for protein identification. The system serves as a one-step purification method for isolation of biologically relevant proteins affected by disease or experimental treatment and has been described in *Electrophoresis* 15, 735–745, 1994. The system includes a preparative isoelectric focusing device for separation of proteins by charge, a glass mold for preparative polyacrylamide gel separation by mass and a protocol for use.

The commercial advantage of the Preparative Two Dimensional Gel Electrophoresis system is to separate and isolate sufficient amounts of individual protein for sequencing in a powerful one-step purification method. The Preparative Two Dimensional Gel Electrophoresis system can resolve individual proteins by charge and mass from up to 1 to 2 mg of unpurified starting material from protein mixtures. Current devices for two dimensional gel electrophoresis are generally for analytical scale work and are not physically or procedurally adapted to accommodate preparative sample loads. Although other preparative electrophoresis devices do exist, they separate by either mass or charge alone and function as stand-alone units without ready integration into additional systems for resolution of individual proteins.

Applications: Protein sequencing, protein immunization for antibody production, immunostaining and other modes of protein characterization.

Development Status: The system has been tested and is operational; however

some refinements in protein resolution are still possible which may involve procedural, reagent or equipment modifications.

Inventors: B. Alex Merrick (*NIEHS*), Rachel Patterson (NIEHS), Robert Hall (NIEHS), Chaoying He (NIEHS), James Selkirk (NIEHS).

Publication: BA Merrick, RM Patterson, LL Witcher, C He, JK Selkirk. Separation and sequencing of familiar and novel murine proteins using preparative two-dimensional gel electrophoresis. *Electrophoresis.* 1994 May;15(5):735–745.

Patent Status: U.S. Patent No. 5,534,121 issued 09 July 1996, claiming priority to 16 May 1994 (HHS Reference No. E–066–1994/0–US–01).

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

Licensing Contact: Michael A. Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov*.

Collaborative Research Opportunity: The NIEHS National Center for Toxicogenomics, Proteomics Group, may consider statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this preparative two-dimensional gel electrophoresis system. Please contact John Penta, NIEHS Office of Translational Research, at 919/541–3696 or *penta@niehs.nih.gov* for additional information.

Dated: December 8, 2006.

Steven M. Ferguson,

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

[FR Doc. E6–21665 Filed 12–19–06; 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.

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 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 shows 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).

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 Betty Tong, PhD at 301–594–4263 for more information.

Vaccine Against *Escherichia Coli* O157 Infection, Composed of Detoxified LPS Conjugated to Proteins

Description of Technology: This invention is a conjugate vaccine to prevent infection by *E. coli* O157:H7, particularly in young children under 5 years of age. *E. coli* O157: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* O157: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* O157, 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% children responded with greater than 10 fold rise of *E. coli* O157 antibodies of bactericidal ability. Thus the conjugates of the invention are