Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person 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 on or before December 17, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 18, 2014.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Stephanie L. Begansky (see Contact Person) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

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

Dated: December 2, 2014.

Jill Hartzler Warner,
Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–28750 Filed 12–8–14; 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, 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. 209 and 37 CFR part 404 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.

FOR FURTHER INFORMATION CONTACT: 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.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

Vaccine for Protection Against Shigella sonnei Disease

Description of Technology: Shigellosis is a global human health problem. Transmission usually occurs by contaminated food and water or through person-to-person contact. The bacterium is highly infectious by the oral route, and ingestion of as few as 10 organisms can cause an infection in volunteers. An estimated 200 million people worldwide suffer from shigellosis, with more than 650,000 associated deaths annually. A recent CDC estimate indicates the occurrence of over 440,000 annual shigellosis cases in the United States alone, approximately eighty percent (80%) of which are caused by Shigella sonnei. Shigella sonnei is more active in developing countries. Shigella infections are typically treated with a course of antibiotics. However, due to the emergence of multidrug resistant Shigella strains, a safe and effective vaccine is highly desirable. No vaccines against Shigella infection currently exist. Immunity to Shigellae is mediated largely by immune responses directed against the serotype specific O-polysaccharide. Claimed in the invention are compositions and methods for inducing an immunoprotective response against S. sonnei. Specifically, an attenuated bacteria capable of expressing an S. sonnei antigen comprised of the S. sonnei form I O-polysaccharide expressed from the S. sonnei rfb/rfc gene cluster is claimed. The inventors have shown that the claimed vaccine compositions showed one hundred percent (100%) protection against parenteral challenge with virulent S. sonnei in mice.

Potential Commercial Applications:

• Shigella/Typhoid vaccine for travelers, military
• Shigella/Typhoid vaccine for developing countries
• Shigella/Typhoid diagnostics

Competitive Advantages:

• Low cost of production
• Temperature stable formulation
• Safety/efficacy of Ty21a established in humans

Development Stage: In vivo data available (animal)

Inventors: Dennis J. Kopecko (FDA), De Qi Xu (NIDCR), John O. Cisar (NICHD)

Salmonella challenge, as well as against virulent Shigella dysenteriae typhi together with homologous Salmonella serotype 1 O-antigen is stably expressed heterologous typhi Ty21a chromosome, where Salmonella of worldwide. dysentery every year, which result in response.

Constructs of this invention and challenge. Also claimed in this application claims a LPS expression of Shigella dysenteriae Salmonella Live Oral Shigellosis Vaccine

Description of Technology: This application claims a Salmonella typhi Ty21a construct comprising a Shigella dysenteriae O-specific polysaccharide (O-Ps) inserted into the Salmonella typhi Ty21a chromosome, where heterologous Shigella dysenteriae serotype 1 O-antigen is stably expressed together with homologous Salmonella typhi O-antigen. The constructs of this invention elicit immune protection against virulent Shigella dysenteriae challenge, as well as Salmonella typhi challenge. Also claimed in this application are methods of making the constructs of this invention and methods for inducing an immune response.

Shigella cause millions of cases of dysentery every year, which result in about seven hundred thousand deaths worldwide. Shigella dysenteriae serotype 1, one of about forty serotypes of Shigella, causes a more severe disease with a much higher mortality rate than other serotypes. There are no licensed vaccines available for protection against Shigella. The fact that many isolates exhibit multiple antibiotic resistance complicates the management of dysentery infections.

Potential Commercial Applications:
- One component of a multivalent anti-shigellosis vaccine under development.
- Shigella vaccines, therapeutics and diagnostics.

Competitive Advantages:
- Vector is well-characterized.
- Simple manufacturing process.
- Potential low-cost vaccine.
- Oral vaccine—avoids need for needles.
- Temperature-stable formulation allows for vaccine distribution without refrigeration.

Development Stage:
- In vitro data available
- In vivo data available (animal)

Inventors: Dennis J. Kopecko and De Qi Xu (FDA/CBER)

- US Patent No. 8,071,113 issued 06 Dec 2011

Licensing Contact: Peter A. Soukas; 301–435–4646; soukasp@mail.nih.gov

Live Oral Shigella dysenteriae Vaccine

Description of Technology: This application claims a Salmonella typhi Ty21a construct comprising a Shigella sonnei O-antigen biosynthetic gene region inserted into the Salmonella typhi Ty21a chromosome, where heterologous Shigella sonnei form 1 O-antigen is stably expressed together with homologous Salmonella typhi O-antigen. The constructs of this invention elicit immune protection against virulent Shigella sonnei challenge, as well as Salmonella Typhi challenge. Also claimed in this application are methods of recombinoid gene into a bacterial chromosome.

Bacillary dysentery and enteric fevers continue to be important causes of morbidity in both developed and developing nations. Shigella causes greater than one hundred and fifty million cases of dysentery and enteric fever occurs in greater than twenty-seven million people annually. Currently, there is no licensed vaccine to prevent the occurrence of shigellosis. Increasing multiple resistance in Shigella commonly thwarts local therapies.

Potential Commercial Applications:
- One component of a multivalent Shigellosis vaccine under development
- Research tool

Competitive Advantages:
- Low cost production
- Lower cost vaccine
- Oral vaccine—no needles required
- Temperature-stable manufacturing process—avoids need for refrigeration during vaccine distribution

Development Stage:
- In vitro data available
- In vivo data available (animal)

Inventors: Dennis J. Kopecko and Madushini N. Dharmasena (FDA/CBER)

- US Provisional Application No. 61/701,939 filed 17 Sep 2012

Licensing Contact: Peter A. Soukas; 301–435–4646; soukasp@mail.nih.gov

Oral Shigellosis Vaccine

Description of Technology: This application claims a Salmonella typhi Ty21a construct comprising a Shigella sonnei O-antigen biosynthetic gene region inserted into the Salmonella typhi Ty21a chromosome, where heterologous Shigella sonnei form 1 O-antigen is stably expressed together with homologous Salmonella typhi O-antigen. The constructs of this invention elicit immune protection against virulent Shigella sonnei challenge, as well as Salmonella Typhi challenge. Also claimed in this application are methods of recombinoid gene into a bacterial chromosome.

Bacillary dysentery and enteric fevers continue to be important causes of morbidity in both developed and developing nations. Shigella causes greater than one hundred and fifty million cases of dysentery and enteric fever occurs in greater than twenty-seven million people annually. Currently, there is no licensed vaccine to prevent the occurrence of shigellosis. Increasing multiple resistance in Shigella commonly thwarts local therapies.

Potential Commercial Applications:
- One component of a multivalent Shigellosis vaccine under development
- Research tool

Competitive Advantages:
- Low cost production
- Lower cost vaccine
- Oral vaccine—no needles required
- Temperature-stable manufacturing process—avoids need for refrigeration during vaccine distribution

Development Stage:
- In vitro data available
- In vivo data available (animal)

Inventors: Madushini N. Dharmasena and Dennis J. Kopecko (FDA/CBER)
Attenuated Salmonella as a Delivery System for siRNA-Based Tumor Therapy

Description of Technology: This technology comprises live, attenuated Salmonella strains as a delivery system for small interfering double-stranded RNA (siRNA)-based tumor therapy. The inventors' data provide the first convincing evidence that Salmonella can be used for delivering plasmid-based siRNAs into tumors growing in vivo. Claimed in the related patent application are methods of inhibiting tumor growth by attenuated Salmonella strains using the si-RNA constructs directed against genes that promote tumor survival and cancer cell growth. The Stat3-siRNAs carried by an attenuated S. typhimurium in the application exhibit tumor suppressive effects not only on the growth of the primary tumor but also on the development of metastases, suggesting that an appropriate attenuated S. typhimurium combined with the RNA interference (RNAi) approach may offer a clinically feasible method for cancer therapy.

Potential Commercial Applications:
- Development of live attenuated bacterial cancer vaccines, cancer therapeutics and diagnostics.
- Developing/developed world vaccine.

Competitive Advantages:
- Low cost of production
- Vaccine vector safety/efficacy in humans established

Development Status: In vivo data available (animal)

Inventors: Dennis J. Kopecko (FDA), De Qi Xu (FDA), Ling Zhang (Jilin University), Jiadi Hu (University of Maryland)

Publications:
5. International Application No. 20061017045.5 filed in China 27 Jul 2006

Licensing Contact: Peter A. Soukas; 301–435–4646; soukasp@mail.nih.gov

DNA Promoters and Anthrax Vaccines

Description of Technology: Currently, the only licensed vaccine against anthrax in the United States is VA BioThrax®, which, although efficacious, suffers from several limitations. This vaccine requires six injectable doses over 18 months to stimulate protective immunity, requires a cold chain for storage, and in many cases has been associated with adverse effects.

This application claims a modified B. anthracis protective antigen (PA) gene for optimal expression and stability, linked it to an inducible promoter for maximal expression in the host, and fused to the secretion signal of the Escherichia coli alpha-hemolysin protein (HlyA) on a low-copy-number plasmid. This plasmid was introduced into the licensed typhoid vaccine strain, Salmonella enterica serovar Typhim strain Ty21a, and was found to be genetically stable. Immunization of mice with three vaccine doses elicited a strong PA-specific serum immunoglobulin G response with a geometric mean titer of 30,000 (range, 5,800 to 157,000) and lethal-toxin-neutralizing titers greater than 16,000. Vaccinated mice demonstrated 100% protection against a lethal intranasal challenge with aerosolized spores of B. anthracis 7702.

Potential Commercial Applications: Anthrax vaccines, therapeutics and diagnostics.

Competitive Advantages:
- Vector is well-characterized.
- Simple manufacturing process.
- Potential low-cost vaccine.
- Oral vaccine—avoids needles and can be administered rapidly during emergencies.
- Temperature-stable manufacturing allows for vaccine distribution without refrigeration.

Development Stage:
- In vitro data available
- In vivo data available (animal)

Inventors: Dennis J. Kopecko, Siba Bhattacharyya, Milan Blake (all of FDA/CBER)


Intellectual Property: HHS Reference No. E–344–2003/1 -
- U.S. Patent No. 7,758,855 issued 20 Jul 2010
- U.S. Patent No. 8,247,225 issued 21 Aug 2012
- U.S. Patent No. 8,709,813 issued 29 Apr 2014
- U.S. Patent Application No. 14/185,353 filed 20 Feb 2014
- Various international patents issued

Licensing Contact: Peter A. Soukas; 301–435–4646; soukasp@mail.nih.gov

Typhoid-Plague Bivalent Vaccine

Description of Technology: Yersinia pestis (Y. pestis) bacteria is the causative agent of plague, typically transmitted from animals to humans by the bite of an infected flea. Y. pestis infection of the lungs leads to pneumonic plague, which is highly contagious and generally fatal. Y. pestis is a potential bioterrorist threat agent for which no vaccine yet exists.

This invention claims the generation and development of a candidate oral vaccine against plague. The vaccine consists of a synthetic gene construct that expresses a Y. pestis F1–V fusion antigen linked to a secretion signal, resulting in the production of large amounts of the F1–V antigen. The F1–V synthetic gene fusion is housed within Ty21a, an attenuated typhoid fever strain that is licensed for human use as a live oral bacterial vaccine. Ty21a serves as a carrier to deliver the F1–V fusion antigens of the plague bacteria; the combined F1–V fusion in the Ty21a carrier has been shown to stimulate a robust immune response in mice. The possibility of combining the oral plague vaccine of this invention with FDA's candidate oral anthrax vaccine exists and would result in an easy-to-administer oral delivery system to streamline administration of the vaccine to large numbers of recipients in emergency situations.

Potential Commercial Applications: Plague vaccines, therapeutics and diagnostics.

Competitive Advantages:
- Vector is well-characterized.
- Simple manufacturing process.
- Potential low-cost vaccine.

Development Stage:
- In vitro data available
- In vivo data available (animal)

Inventors: Dennis J. Kopecko, Manuel A. Osorio, Monica R. Foote (all of FDA/CBER)

- U.S. Provisional Application No. 61/650,676 filed 23 May 2012

Potential Commercial Applications:
- Plague vaccines, therapeutics and diagnostics.
- Competitive Advantages:
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and AIDS Related Research.

Date: December 15, 2014.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Mary Clare Walker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435–1165, walkermc@csr.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: Center for Scientific Review Special Emphasis Panel; Special Topics in HIV/AIDS Behavioral Research.

Date: December 18, 2014.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Mark P Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1775, rubertm@csr.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: Center for Scientific Review Special Emphasis Panel; Pathologies in the Nervous System.

Date: December 18, 2014.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Peter B Guthrie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC 7850, Bethesda, MD 20892, (301) 435–1239, guthriep@csr.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.


David Clary,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–28752 Filed 12–8–14; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: Center for Scientific Review Special Emphasis Panel; Special Topic: Small Business Innovative Research.

Date: December 18, 2014.

Time: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Andrea Keane-Myers, BS, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4218, Bethesda, MD 20892, 301–435–1221, andrea.keane-myers@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.


David Clary,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–28748 Filed 12–8–14; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as