520(g) of the act for human tests to begin became effective April 11, 1997.

2. *The date an application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: October 18, 2007. FDA has verified the applicant's claim that the premarket approval application (PMA) for TALENT ABDOMINAL STENT GRAFT SYSTEM (PMA P070027) was initially submitted October 18, 2007.

3. *The date the application was approved*: April 15, 2008. FDA has verified the applicant's claim that PMA P070027 was approved on April 15, 2008.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,183 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by November 3, 2009. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 3, 2010. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 8, 2009.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E9–21424 Filed 9–3–09; 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.

Antigenic Chimeric Tick-Borne Encephalitis Virus/Dengue Virus Type 4 Recombinant Viruses

Description of Technology: The tick-borne encephalitis virus (TBEV) complex is a group of viruses that can cause severe neutrotropic disease and up to thirty percent (30%) mortality. While these viruses can be found in many parts of the world, the largest impact of the disease occurs in Europe and Russia, where approximately fourteen thousand (14,000) hospitalized TBEV cases occur annually. TBEV is in the family Flaviviridae, genus flavivirus and is composed of a positive-sense single stranded RNA genome that contains 5′ and 3′ non-coding regions and a single open reading frame encoding ten (10) proteins. At present, a vaccine or FDA approved antiviral therapy is not available.

The inventors have previously developed a WNV/Dengue4Delta30 antigenic chimeric virus as a live attenuated virus vaccine candidate that contains the WNV premembrane and envelope (prM and E) proteins on a dengue virus type 4 (DEN4) genetic background with a thirty nucleotide deletion (Delta30) in the DEN4 3′-UTR. Using a similar strategy, the inventors have generated an antigenic chimeric virus, TBEV/DEN4Delta30. This chimeric virus also contains attenuating mutations within the E and nonstructural NS5 proteins. Preclinical testing results with the derived virus indicate that chimerization of TBEV with DEN4Delta30 and introduction of the attenuating mutations decreased neuroinvasiveness and neurovirulence in mice. The TBEV/DEN4delta30 vaccine candidate was safe, immunogenic, and provided protection in monkeys against challenge with TBE viruses.

This application claims live attenuated chimeric TBEV/DEN4Delta30 vaccine compositions. Also claimed are methods of treating or preventing TBEV infection in a mammalian host, methods of producing a subunit vaccine composition, isolated polynucleotides comprising a nucleotide sequence encoding a TBEV immunogen, methods for detecting TBEV infection in a biological sample and infectious chimeric TBEV.

Applications: Development of Tick-Borne Encephalitis Virus vaccines, therapeutics and diagnostics.

Advantages: Live attenuated chimeric vaccine, known regulatory pathway, potential for lasting immunity with fewer doses.

Development Status: Vaccine candidates have been synthesized and preclinical studies have been performed.

Inventors: Alexander G. Pletnev, Amber R. Engel, Brian R. Murphy (NIAID).

Patent Status: U.S. Provisional Application No. 61/181,982 filed 28 May 2009 (HHS Reference No. E–078–2009/0–US–01).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The NIAID is seeking statements of capability or interest from parties interested in collaborative research in preclinical study of the long-term immunity induced by the TBEV/DEN4 vaccine candidate against highly virulent TBE viruses and in the clinical trials of this vaccine in humans. Please contact Michael Piziali, NIAID Office of Technology Development, at 301–496–2644 for more information.

Monoclonal Antibodies That React With the Capsule of *Bacillus anthracis*

Description of Technology: Bacillus anthracis is the causative agent of anthrax and is surrounded by a

polypeptide capsule of poly-γ-D-glutamic acid (γDPGA). γDPGA is poorly immunogenic and has antiphagocytic properties. The bacterial capsule is essential for virulence. Antibodies to the capsule have been shown to enhance phagocytosis and killing of encapsulated bacilli. These antibodies in combination with antibodies that neutralize the toxins of *B. anthracis* could provide enhanced protection by their dual antibacterial and antitoxic activities. Such antibodies would be especially useful for antibiotic-resistant strains.

In order to obtain therapeutically useful anti-γ DPGA monoclonal antibodies (MAbs), the inventors immunized chimpanzees with conjugates of 15-mer glutamic acid polymers to immunogenic protein carriers (recombinant protective antigen (PA) of *B. anthracis*). After several immunizations, chimpanzees developed strong immune responses to γDPGA. A combinatorial Fab library of mRNA derived from the chimpanzee's bone marrow was prepared and eight (8) distinct Fabs reactive with native γDPGA were recovered. Two (2) of the Fabs were converted into full-length IgG with human γ1 heavy chain constant regions. These two (2) MAbs showed strong opsonophagocytic killing of bacilli in an *in vitro* assay. These two (2) MAbs were also tested for protection of mice challenged with virulent anthrax spores and results showed that both MAbs provided full or nearly full protection at a dose of 0.3 mg, the lowest dose tested, which is much more potent than previously reported murine anti-PGA MAbs. Since chimpanzee immunoglobulins are virtually identical to human immunoglobulins, these chimpanzee anticapsule MAbs may have clinically useful applications.

This application claims the antibody compositions described above. Also claimed are methods of treating or preventing *B. anthracis* infection in a mammalian host and isolated polynucleotides comprising a nucleotide sequence encoding the antibodies of the technology.

Applications: Development of anthrax vaccines, therapeutics and diagnostics.

Advantages: Strongly neutralizing antibodies, known regulatory pathway, potential for use as both a prophylaxis and therapy.

Development Status: Preclinical studies have been performed utilizing the monoclonal antibodies of this technology.

Inventors: Zhaochun Chen (NIAID), Robert H. Purcell (NIAID), Joanna Kubler-Kielb (NICHD), Lily Zhongdong Dai (NICHD), Rachel Schneerson (NICHD).

Patent Status: U.S. Provisional Application No. 61/116,222 filed 19 Nov 2008 (HHS Reference No. E–125–2008/0–US–01).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The NIAID is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize MAbs neutralizing anthrax toxins and capsule for comprehensive protection against anthrax. Please contact Bill Ronnenberg, NIAID Office of Technology Development, at 301–451–3522 for more information.

Dated: August 28, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–21482 Filed 9–3–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Health Promotion and Disease Prevention Research Centers, Special Interest Project Competitive Supplements (SIPS) (U48 Panels A–M), RFA–DP09–101SUPP09, Initial Review

Cancellation: The notice was originally published in the **Federal Register** on July 14, 2009 (Volume 74, Number 133) [page 34026]. The following panels are cancelled: D, F, K, L and M.

Contact Person for More Information: Brenda Colley-Gilbert, PhD, Director, Extramural Research Program Office, CCCH, 4770 Buford Highway, MS K–92, Atlanta, GA 30341, Telephone (770) 488–6295.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: August 26, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E9–21379 Filed 9–3–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0233]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: Under the Food and Drug Administration Modernization Act of 1997 (Modernization Act), the Food and Drug Administration (FDA) is required to report annually in the **Federal Register** on the status of postmarketing requirements and commitments required of, or agreed upon, by holders of approved drug and biological products. This is the agency's report on the status of the studies and clinical trials that applicants have agreed to or are required to conduct.

FOR FURTHER INFORMATION CONTACT:

Cathryn C. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6464, Silver Spring, MD 20993–0002, 301–796–0700; or

Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1400 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Modernization Act

Section 130(a) of the Modernization Act (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding a new provision requiring reports of certain postmarketing studies, including clinical trials, for human drug and biological products (section 506B of the act (21 U.S.C. 356(b)). Section 506B of the act provides FDA with additional authority to monitor the progress of a postmarketing study or clinical trial that an applicant has been required to or has agreed to conduct by requiring the applicant to submit a report annually