2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: November 17, 2005. FDA has verified the applicant's claim that the new drug application (NDA) 21–911 for BANZEL was initially submitted on November 17, 2005.

3. *The date the application was approved*: November 14, 2008. FDA has verified the applicant's claim that NDA 21–911 was approved on November 14, 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 819 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 23, 2009.

Jane A. Axelrad,

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

[FR Doc. E9–21428 Filed 9–3–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–E–0568]

Determination of Regulatory Review Period for Purposes of Patent Extension; TALENT ABDOMINAL STENT GRAFT SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TALENT ABDOMINAL STENT GRAFT SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device, TALENT ABDOMINAL STENT GRAFT SYSTEM. The TALENT ABDOMINAL STENT GRAFT SYSTEM is indicated for the endovascular treatment of abdominal aortic aneurysms with or without iliac involvement having: Iliac/femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories; a proximal aortic neck length of ≥ 10 millimeters (mm); proximal aortic neck angulation ≤ 60° distal iliac artery fixation length of ≥ 15 mm; an aortic neck diameter of 18 to 32 mm and iliac artery diameters of 8 to 22 mm; and vessel morphology suitable for endovascular repair. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TALENT ABDOMINAL STENT GRAFT SYSTEM (U.S. Patent No. 6,306,141) from Medtronic, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 18, 2009, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of TALENT ABDOMINAL STENT GRAFT SYSTEM represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for TALENT ABDOMINAL STENT GRAFT SYSTEM is 4,024 days. Of this time, 3,843 days occurred during the testing phase of the regulatory review period, while 181 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective*: April 11, 1997. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section

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