indicate that the IND effective date was December 24, 1992, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: September 27, 2002. FDA has verified the applicant's claim that the new drug application (NDA) for ALOXI (NDA 21–372) was initially submitted on September 27, 2002.

3. *The date the application was approved*: July 25, 2003. FDA has verified the applicant's claim that NDA 21–372 was approved on July 25, 2003.

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 1,827 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 April 3, 2006. 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 August 1, 2006. 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: January 5, 2006.

Jane A. Axelrad,

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

[FR Doc. 06–903 Filed 2–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2005E–0258, 2005E–0247, and 2005E–0233]

Determination of Regulatory Review Period for Purposes of Patent Extension; OMACOR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for OMACOR and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of three applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of three patents that claim that human drug product.

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.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6681.

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 human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. 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 (for example, 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 human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product OMACOR (omega–3–acid ethyl esters). OMACOR is indicated as an adjunct to diet to reduce very high (= 500 milligrams per deciliter) triglyceride levels in adult patients. Subsequent to this approval, the Patent and Trademark Office received three patent term restoration applications for OMACOR (U.S. Patent Nos. 5,656,667, 5,698,594, and 5,502,077) from Pronova Biocare AS, and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated July 8, 2005, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of OMACOR 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 OMACOR is 3,712 days. Of this time, 3,408 days occurred during the testing phase of the regulatory review period, while 304 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: September 14, 1994. The applicant claims August 15, 1994, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 14, 1994, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: January 12, 2004. FDA has verified the applicant's claim that the new drug application (NDA) for OMACOR (NDA 21–654) was initially submitted on January 12, 2004.

3. *The date the application was approved*: November 10, 2004. FDA has verified the applicant's claim that NDA

21–654 was approved on November 10, 2004.

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 applications for patent extension, this applicant seeks 1,477 (U.S. Patent No. 5,656,667), 1,413 (U.S. Patent No. 5,698,594), and 1,728 (U.S. Patent No. 5,502,077) days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 3, 2006. 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 August 1, 2006. 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: January 5, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–1365 Filed 2–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Emerging Infectious Diseases Laboratories Record of Decision

ACTION: Notice.

SUMMARY: The Department of Health and Human Services, the National Institutes of Health (NIH), has decided, after completion of a Final Environmental Impact Statement (FEIS) and a thorough consideration of the public comments on the Draft EIS and Supplemental EIS, to implement the Proposed Action, which is identified as the Preferred Alternative in the Final EIS. This action is to partially fund the construction of a state-of-the-art National Biocontainment Laboratory (NBL), to be called the National Emerging Infectious Diseases Laboratories (NEIDL), at the Boston University Medical Center (BUMC) Campus in Boston, Massachusetts.

FOR FURTHER INFORMATION CONTACT: Valerie Nottingham, Chief of the Environmental Quality Branch, Division of Environmental Protection, Office of Research Facilities Development and Operations, NIH, Building 13, Room 2W64, 9000 Rockville Pike, Bethesda, MD 20892, Fax 301–480–8056, e-mail *nihnepa@mail.nih.gov.*

SUPPLEMENTARY INFORMATION:

Decision

After careful review of the environmental consequences in the Final Environmental Impact Statement for the National Emerging Infectious Diseases Laboratories (Final NEIDL EIS), and consideration of public comment throughout the NEPA process, the NIH has decided to implement the Proposed Action described below as the Selected Alternative.

Selected Alternative

The NIH plans to partially fund the construction of a state-of the art National Biocontainment Laboratory, which will be known as the National Emerging Infectious Diseases Laboratories (NEIDL), on the Boston University Medical Center Campus in Boston, Massachusetts. The NIH will fund approximately $128 million dollars. The proposed NEIDL will enhance national security through the development and evaluation of improved diagnostics, therapeutics, and vaccines for the protection against naturally emerging and re-emerging diseases, including those that have the potential for bioterrorism. The proposed NEIDL will not conduct research to develop biological weapons.

The proposed NEIDL facility will be a new steel and reinforced concrete seven-story building that will be constructed within the BioSquare Research Park, with a total assignable area of 84,100 square feet, and will house Biosafety Level (BSL)–4, BSL–3, and BSL–2 facilities, BSL–4 and BSL–3 animal facilities, an Arthropod Containment Level (ACL)–3 insectary, offices, conference rooms, and support facilities including an effluent treatment room, secure loading dock, and dedicated mechanical floors to enhance containment features of the building.

The proposed NEIDL facility will be designed to safely support all the superimposed loads applied to the building and will be constructed to the requirements of Seismic Performance Category C, which assures that the building structure stays functional after a seismic event. In addition to standby generators to provide power in the event of a power outage, the NEIDL facility will have a distributed on-line uninterruptible power supply to power the BSL–4 laboratory biosafety cabinets, critical building control panels and alarms. The four biosafety levels have increasingly stringent design, security, and containment requirements. The safety levels are determined based on the biological materials used in research and the ways they affect the human population. BSL–1 facilities have no requirements for safety equipment, while BSL–4 facilities have extensive and multiple requirements for safety equipment and facility design such as isolation, buffer zones, airflow and pressure requirements, and high efficiency particulate air (HEPA) filtration.

The building also will be provided with an environmental monitoring system to assess room pressure differentials (to ensure negative pressure in the biocontainment areas), smoke detection, and the pressure drop condition HEPA filters. Visual indicators (such as pressure gauges) and audible or strobic alarms will alert NEIDL personnel in the event of an emergency or situation that requires corrective action or other response. The NEIDL will have fire protection systems that meet or exceed requirements specified by the National Fire Protection Association and all applicable local, state, Federal, and BUMC requirements.

The design of the proposed NEIDL facility's BSL–4, –3, and –2 laboratories will comply with the recommendations and requirements of the Centers for Disease Control (CDC) and the NIH joint publication addressing biosafety in laboratories, the current edition Biosafety in Microbiological and Biomedical Laboratories, as well as NIH's Design Policies and Guidelines for Biomedical Research Laboratories. The BSL–4, –3, –2 animal laboratories will further comply with the recommendations and requirements of the latest edition of Guide for Care and Use of Laboratory Animals, published by the National Research Council.

The BSL–4 laboratory environment employs the concept of a ''box-within-a-box'' principle, whereby the laboratory is built within a pressure-