

collection techniques or other forms of information technology.

**Direct Comments to OMB:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA\_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Gina Wei, Division of Cardiovascular Sciences, NHLBI, NIH, Two Rockledge Center, 6701 Rockledge Drive, MSC 7936, Bethesda, MD, 20892-7936, or call non-toll-free number (301) 435-0456, or e-mail your request, including your address to: *weig@nhlbi.nih.gov*.

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: September 1, 2010.

**Suzanne Freeman,**

*NHLBI Project Clearance Liaison, National Institutes of Health.*

**Michael Lauer,**

*Director, DCVS, National Institutes of Health.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-E-0414]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; REPEL-CV

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for REPEL-CV 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 electronic comments to <http://www.regulations.gov>. Submit written petitions along with three copies and written comments to the Division of

Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**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, REPEL-CV. REPEL-CV, a bioresorbable adhesion barrier, is indicated for reducing the severity of post-operative cardiac adhesions in pediatric patients who are likely to require reoperation via sternotomy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for REPEL-CV (U.S. Patent No. 5,711,958) from SyntheMed, 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 17, 2010, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period

and that the approval of REPEL-CV represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for REPEL-CV is 4,023 days. Of this time, 3,256 days occurred during the testing phase of the regulatory review period, while 767 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:* March 3, 1998. 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 March 3, 1998.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e):* January 30, 2007. FDA has verified the applicant's claim that the premarket approval application (PMA) for REPEL-CV (PMA P070005) was initially submitted January 30, 2007.

3. *The date the application was approved:* March 6, 2009. FDA has verified the applicant's claim that PMA P070005 was approved on March 6, 2009.

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 1,742 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**) either electronic or written comments and ask for a redetermination by November 8, 2010. 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 8, 2011. 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.

Interested persons may submit to the Division of Dockets Management (see

**ADDRESSES)** electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 13, 2010.

**Jane A. Axelrad,**

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

[FR Doc. 2010-22496 Filed 9-8-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-E-0416]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; IXIARO

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for IXIARO 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 human biological product.

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

**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 human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product IXIARO (Japanese Encephalitis Virus, Vaccine Inactivated, Adsorbed). IXIARO is indicated for active immunization for the prevention of disease caused by Japanese encephalitis virus in persons 17 years of age and older. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for IXIARO (U.S. Patent No. 6,309,650) from Chiel Jedang Corp. and Walter Reed Army Institute of Research, 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 17, 2010, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of IXIARO 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 IXIARO is 3,461 days. Of this time,

2,994 days occurred during the testing phase of the regulatory review period, while 467 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 (21 U.S.C. 355(i)) became effective:* October 10, 1999. The applicant claims October 9, 1999, as the date the investigational new drug application (IND) became effective.

However, FDA records indicate that the IND effective date was October 10, 1999, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* December 20, 2007. FDA has verified the applicant's claim that the biologics license application (BLA) for IXIARO (BLA B125280/0) was initially submitted on December 20, 2007.

3. *The date the application was approved:* March 30, 2009. FDA has verified the applicant's claim that BLA B125280/0 was approved on March 30, 2009.

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 1,588 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**) either electronic or written comments and ask for a redetermination by November 8, 2010. 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 8, 2011. 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.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with