SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 has approved for marketing the human biological product EYLEA (aflibercept). EYLEA is indicated for the treatment of patients with neovascular (Wet) Age-Related Macular Degeneration (AMD). Subsequent to this approval, the U.S. Patent and Trademark Office received patent term restoration applications for EYLEA (U.S. Patent Nos.: 7,070,959; 7,374,757; and 7,374,758) from Regeneron Pharmaceuticals, Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated August 7, 2012, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of EYLEA 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 EYLEA is 2,349 days. Of this time, 2,075 days occurred during the testing phase of the regulatory review period, while 274 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 FD&C Act) (21 U.S.C. 355(i)) became effective:* June 15, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 15, 2005.

2. *The date the application was initially submitted with respect to the human drug product under section 352 of the Public Health Service Act (42 U.S.C. 262):* February 18, 2011. The applicant claims February 17, 2011, as the date the biologics license application (BLA) for EYLEA (BLA 125387/0) was initially submitted. However, FDA records indicate that BLA 125387/0 was submitted on February 18, 2011.

3. *The date the application was approved:* November 18, 2011. FDA has verified the applicant's claim that BLA 125387/0 was approved on November 18, 2011.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the 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 either 775 or 1,118 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 June 2, 2014. 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 September 29, 2014. 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 electronic or written petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07333 Filed 4–1–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–E–0716]

Determination of Regulatory Review Period for Purposes of Patent Extension; NOVOTFF–100A SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for NOVOTFF–100A 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 electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA 2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 has approved for marketing the medical device, NOVOTFF–100A SYSTEM. NOVOTFF–100A SYSTEM is indicated for treatment of adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM), following histologically- or radiologically-confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for NOVOTFF–100A SYSTEM (U.S. Patent No. 7,136,699) from Novocure Limited, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 10, 2012, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of NOVOTFF–100A SYSTEM 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 NOVOTFF–100A SYSTEM is 1,704 days. Of this time, 1,468 days occurred during the testing phase of the regulatory review period, while 236 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 FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* August 10, 2006. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective August 10, 2006.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* August 16, 2010. The applicant claims December 30, 2009, as the date the premarket approval application (PMA) NOVOTFF–100A System] (PMA P100034) was initially submitted. However, FDA records indicate that PMA P100034 was a modular submission and the final module was received by FDA on August 16, 2010.

3. *The date the application was approved:* April 8, 2011. FDA has verified the applicant's claim that PMA P100034 was approved on April 8, 2011.

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 807 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 June 2, 2014. 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 September 29, 2014. 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 or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA 2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07329 Filed 4–1–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Ryan White HIV/AIDS Program, Part C Early Intervention Services Grant Under the Ryan White HIV/AIDS Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of Ryan White HIV/AIDS Program Part C Early Intervention Services One-time Noncompetitive Replacement Award to Ensure Continued HIV Primary Medical Care.

SUMMARY: To prevent a lapse in comprehensive primary care services for more than 200 persons living with HIV/AIDS, HRSA will provide a one-time noncompetitive Ryan White HIV/AIDS Program Part C award to St. Luke's Hospital, Bethlehem, Pennsylvania.

SUPPLEMENTARY INFORMATION: The amount of the award to ensure ongoing HIV medical services is $294,399.

Authority: Section 2651 of the Public Health Service (PHS) Act, 42 U.S.C. 300ff–51.

CFDA Number: 93.918.

Project period: The period of support for this award is 12 months, explained below in further detail.

Justification for the Exception to Competition: The Two Rivers Health and Wellness Foundation, Easton, Pennsylvania (H76HA00774) announced the relinquishment of their Part C grant on December 27, 2013. Grant funds of $294,399 are to be awarded to St. Luke's Hospital, Bethlehem, PA, to prevent a lapse in HIV medical services. St. Luke's Hospital has been determined to be eligible to receive the Part C grant to provide interim HIV medical care. To prevent a lapse in HIV medical care,