

3. *The date the application was approved:* March 25, 2011. FDA has verified the applicant's claim that BLA 125377/0 was approved on March 25, 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 966 or 398 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 30, 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 October 28, 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: April 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09910 Filed 4–30–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–E–0154]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for EDURANT 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 drug product.

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, 301–796–7900.

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 drug product EDURANT (rilpivirine hydrochloride). EDURANT is indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV–1) infection in treatment-naïve adult patients. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for EDURANT (U.S. Patent No. 7,125,879) from Janssen Pharmaceutica N.V., 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 human drug product had undergone a regulatory review period and that the approval of EDURANT 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 EDURANT is 2,396 days. Of this time, 2,094 days occurred during the testing phase of the regulatory review period, while 302 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:* October 29, 2004. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 29, 2004.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* July 23, 2010. FDA has verified the applicant's claim that the new drug application (NDA) for EDURANT (NDA 202022) was submitted on July 23, 2010.

3. *The date the application was approved:* May 20, 2011. FDA has verified the applicant's claim that NDA 202022 was approved on May 20, 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 application for patent extension, this applicant seeks 768 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 30, 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 October 28, 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: April 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09911 Filed 4–30–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection

Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than June 30, 2014.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: National Health Service Corps Site Application and Site Recertification Application.

OMB No. 0915–0230—Revision.

Abstract: The National Health Service Corps (NHSC) of the Bureau of Clinician Recruitment and Service (BCRS), Health Resources and Services Administration, is committed to improving the health of the nation's underserved by uniting communities in need with caring health professionals, and by supporting their efforts to build better systems of care. NHSC-approved sites are health care facilities that provide comprehensive outpatient, ambulatory, primary health care services to populations residing in Health Professional Shortage Areas

(HPSAs). Related inpatient services may be provided by NHSC-approved Critical Access Hospitals (CAHs). In order to become an NHSC-approved site, new sites must submit a Site Application for review and approval. Existing NHSC-approved sites are required to complete a Site Recertification Application in order to maintain their status as an approved site. Both the NHSC Site Application and Site Recertification Application request information on the clinical service site, sponsoring agency, recruitment contact, staffing levels, service users, charges for services, employment policies, and fiscal management capabilities. Assistance in completing these applications may be obtained through the appropriate State Primary Care Offices and the NHSC. The information collected on the applications is used for determining the eligibility of sites for the assignment of NHSC health professionals and to verify the need for NHSC clinicians. Approval as an NHSC service site is valid for 3 years. Sites wishing to remain eligible for the assignment of NHSC providers, must submit a Site Recertification Application every 3 years.

Need and Proposed Use of the Information: The need and purpose of this information collection is to obtain information for NHSC site applicants. The information obtained from the NHSC Site Application and Site Recertification Application will be utilized to determine the eligibility of sites to participate in the NHSC as an approved service site.

Likely Respondents: Health care facilities interested in participating in the NHSC and becoming an approved service site.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours: