

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Nonprofit Capacity Building Program Performance Progress Report (PPR) .....	35	4	1	140
Government Capacity Building Program PPR .....	49	4	1	196

Estimated Total Annual Burden Hours: 336.

**Additional Information:**

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address:* [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

**OMB Comment:** OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202-395-7285, *E-mail:* [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV). *Attn:* Desk Officer for the Administration for Children and Families.

Dated: August 31, 2010.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2010-22132 Filed 9-3-10; 8:45 am]

**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0436]

**Center for Biologics Evaluation and Research eSubmitter Pilot Evaluation Program for Blood Establishments That Collect Whole Blood and Blood Components**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER) is announcing an invitation to participate in a pilot evaluation program

for CBER's eSubmitter Program (eSubmitter). CBER's eSubmitter has been customized as an automated biologics license application (BLA) and BLA supplement (BLS) submission system for blood and blood components. Participation in the pilot program is open to blood establishments that collect Whole Blood and blood components. The pilot program is intended to provide industry and CBER regulatory review staff the opportunity to evaluate the eSubmitter system and determine if it facilitates the BLA/BLS submission process. The purpose of this notice is to invite blood establishments that collect Whole Blood and blood components to submit a request to CBER if they are interested in participating in this pilot program.

**DATES:** Submit a written or electronic request for participation in this program by October 7, 2010.

**ADDRESSES:** If you are interested in participating in this program, you should submit a request to participate in the program to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Lore Fields, Center for Biologics Evaluation and Research (HFM-375), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6143, FAX: 301-827-3534, email: [lore.fields@fda.hhs.gov](mailto:lore.fields@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

CBER regulates certain biological products, including blood and blood products, and is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness and timely delivery of these products to patients. Further, CBER seeks to continuously enhance and update review efficiency and quality, and the quality of its regulatory efforts and interactions, by providing CBER staff and industry with improved processes. In support of this goal, CBER has participated in the FDA development of a computer-assisted automated BLA/BLS submission program called eSubmitter to improve

the process for providing certain regulatory submissions to FDA. eSubmitter will include programs to submit applications for licensure, supplements to an approved license, and amendments to pending applications or supplements.

**II. The eSubmitter Pilot Evaluation Program Expectations**

The eSubmitter pilot evaluation program is expected to last approximately 12 months. During this period of time, participants will complete BLA/BLS regulatory submissions using the eSubmitter template developed at CBER for use by blood establishments that collect Whole Blood and blood components. eSubmitter was developed using the same review criteria for applications for these products as currently used in the BLA/BLS review process at CBER. During the BLA/BLS submission process, the participants will enter the requested information into the eSubmitter tool and attach requested documents as an Adobe document (pdf format). This information will be saved onto a CD-ROM and mailed to CBER for review. Paper copies of submissions will not be required. CBER will review the information provided on the CD-ROM and the attachments according to current managed review procedures.

During the BLA/BLS submission process, CBER staff will be available to answer any questions or concerns that may arise. As each submission is completed, the users will be asked to comment on the eSubmitter program. These discussions will assist CBER in the final development and release of this electronic tool for use by industry.

**III. Requests for Participation**

Requests to participate in the eSubmitter pilot are to be identified with the docket number found in brackets in the heading of this document. You should include the following information in your request: Contact name, contact phone number, email address, name of the establishment, address, and license number. Once requests for participation are received, FDA will contact interested establishments to discuss the pilot program.

Dated: August 31, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-22167 Filed 9-3-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-E-0048]

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

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for EFFIENT 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 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 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 EFFIENT (Prasugrel Hydrochloride). EFFIENT is a platelet inhibitor indicated for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndrome who are to be managed with percutaneous coronary intervention. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for EFFIENT (U.S. Patent No. 5,288,726) from Daiichi Sankyo Co. Ltd., and UBE Industries, Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 24, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of EFFIENT 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 EFFIENT is 2,795 days. Of this time, 2,232 days occurred during the testing phase of the regulatory review period, while 563 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:* November 16, 2001. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 16, 2001.

2. *The date the application was initially submitted with respect to the*

*human drug product under section 505(b) of the act:* December 26, 2007. FDA has verified the applicant's claim that the new drug application (NDA) for EFFIENT (NDA 22-307) was submitted on December 26, 2007.

3. *The date the application was approved:* July 10, 2009. FDA has verified the applicant's claim that NDA 22-307 was approved on July 10, 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 1,679 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 7, 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 [www.regulations.gov](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: August 13, 2010.

**Jane A. Axelrad,**

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

[FR Doc. 2010-22234 Filed 9-3-10; 8:45 am]

**BILLING CODE 4160-01-S**