

Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 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. 6250, Silver Spring, MD 20993, 301-796-3600.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

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 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 USPTO 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 has approved for marketing the human biologic product ALPROLIX (Coagulation Factor IX (Recombinant), Fc Fusion Protein). ALPROLIX is a recombinant DNA derived, coagulation Factor IX concentrate indicated in adults and children with hemophilia B for control and prevention of bleeding episodes, perioperative management, and routine prophylaxis to prevent or reduce the frequency of bleeding episodes. Subsequent to this approval, the USPTO received patent term restoration applications for ALPROLIX (U.S. Patent Nos. 7,348,004, 7,862,820, and 8,329,182) from Biogen Idec Hemophilia Inc., and the USPTO requested FDA’s assistance in determining the patents’ eligibility for patent term restoration. In a letter dated May 11, 2015, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of ALPROLIX represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

**II. Determination of Regulatory Review Period**

FDA has determined that the applicable regulatory review period for ALPROLIX is 2,223 days. Of this time, 1,767 days occurred during the testing phase of the regulatory review period, while 456 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:* February 27, 2008. FDA has verified the applicant’s claim that the date the investigational new drug application (IND) became effective was on February 27, 2008.

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 28, 2012. FDA has verified the applicant’s claim that the biologics license application (BLA) for ALPROLIX (BLA 125444/0) was initially submitted on December 28, 2012.

3. *The date the application was approved:* March 28, 2014. FDA has verified the applicant’s claim that BLA 125444/0 was approved on March 28, 2014.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,326 days, 465 days, or 818, days, respectively, of patent term extension.

**III. Petitions**

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). 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. To meet its burden, the petition must be timely (see **DATES**) and 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.

Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 2, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-13526 Filed 6-7-16; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. FDA-2014-E-2365, FDA-2014-E-2368, FDA-2014-E-2367, and FDA-2014-E-2366]

**Determination of Regulatory Review Period for Purposes of Patent Extension; ELOCTATE**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for ELOCTATE and is publishing this notice of that determination as required

by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of patents which claim that human biological product.

**DATES:** Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by August 8, 2016. 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 December 5, 2016. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your

comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket Nos. FDA-2014-E-2365, FDA-2014-E-2368, FDA-2014-E-2367, and FDA-2014-E-2366 for "Determination of Regulatory Review Period for Purposes of Patent Extension; ELOCTATE." Received comments will be placed in the dockets and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

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#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

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 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 USPTO 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 has approved for marketing the human biologic product ELOCTATE (BDD-rFVIII(Fc)). ELOCTATE is a recombinant DNA derived, antihemophilic factor indicated in adults and children with Hemophilia A (congenital Factor VIII deficiency) for control and prevention of bleeding episodes, perioperative management, and routine prophylaxis to prevent or reduce the frequency of bleeding episodes. Subsequent to this approval, the USPTO received patent term restoration applications for ELOCTATE (U.S. Patent Nos. 7,348,004; 7,404,956; 7,862,820; and 8,329,182) from Biogen Idec Hemophilia Inc., and the USPTO requested FDA's assistance in

determining this patent's eligibility for patent term restoration. In a letter dated October 19, 2015, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of ELOCTATE represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

## II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ELOCTATE is 1,695 days. Of this time, 1,239 days occurred during the testing phase of the regulatory review period, while 456 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 17, 2009. The applicant claims December 10, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 17, 2009, 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):* March 8, 2013. The applicant claims March 7, 2013, as the date the biologics license application (BLA) for ELOCTATE (BLA 125487/0) was initially submitted. However, FDA records indicate that BLA 125487/0 was submitted on March 8, 2013.

3. *The date the application was approved:* June 6, 2014. FDA has verified the applicant's claim that BLA 125487/0 was approved on June 6, 2014.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,049 days, 740 days, 854 days, or 500 days, respectively, of patent term extension.

## III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). 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. To meet its burden, the petition must be timely (see **DATES**) and 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.

Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 2, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-13521 Filed 6-7-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Service Administration

#### Advisory Committee on Training in Primary Care Medicine and Dentistry; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

*Name:* Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD).

*Dates and Times:* June 28, 2016 (Day 1—8:30 a.m.–5:00 p.m., EST), June 29, 2016 (Day 2—8:30 a.m.–5:00 p.m., EST).

*Place:* In-Person Meeting with Webinar/Conference Call Component, 5600 Fishers Lane, Room 5E29, Rockville, MD 20857.

*Status:* The meeting will be open to the public.

*Purpose:* The ACTPCMD provides advice and recommendations on a broad range of issues relating to grant programs authorized by title VII, part C, sections 747 and 748 of the Public Health Service Act (PHSA). During the June 28–29, 2016 meeting, the Committee will discuss the topic for the 14th report which is divided into two areas: a) Review of Primary Care Medicine and Dentistry Programs under title VII, part C of the PHSA and b) the ways to integrate behavioral health content into primary care medicine and dentistry training programs.

*Agenda:* The purpose of the Advisory Committee meeting is two-fold: a) Review the activities under sections 747 and 748, part C of title VII of the PHSA Act including performance measures, longitudinal evaluations, and

appropriation levels for these programs; and b) review ways that behavioral health content could be integrated into primary care education and training. The Committee has identified that integrating behavioral health services into primary care settings offers a promising, viable, and efficient way of ensuring that people have access to needed behavioral health services. The ACTPCMD's reports are submitted to the Secretary of the Department of Health and Human Services; the Committee on Health, Education, Labor, and Pensions of the Senate; and the Committee on Energy and Commerce of the House of Representatives. The ACTPCMD agenda will be available 2 days prior to the meeting on the HRSA Web site at <http://www.hrsa.gov/advisorycommittees/bhpradvisory/actpcmd/index.html>.

**SUPPLEMENTARY INFORMATION:** Requests to make oral comments or provide written comments to the ACTPCMD should be sent to Dr. Joan Weiss, Designated Federal Official, using the address and phone number below. Individuals who plan to make oral comments or provide written comments to the ACTPCMD should notify Dr. Weiss at least 3 days prior to the meeting, using the address or phone number below. Members of the public will have the opportunity to provide comments. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Dr. Weiss at least 10 days prior to the meeting.

- The conference call-in number is 1-800-619-2521. The passcode is 9271697.

- The webinar link is <https://hrsa.connectsolutions.com/actpcmd>.

*Contact:* Anyone requesting information regarding the ACTPCMD should contact Dr. Joan Weiss, Designated Federal Official within the Bureau of Health Workforce, Health Resources and Services Administration, in one of three ways: (1) Send a request to the following address: Dr. Joan Weiss, Designated Federal Official, Bureau of Health Workforce, Health Resources and Services Administration, 5600 Fishers Lane, Room 15N39, Rockville, Maryland 20857; (2) call (301) 443-0430; or (3) send an email to [jweiss@hrsa.gov](mailto:jweiss@hrsa.gov).

**Jason Bennett,**

*Director, Division of the Executive Secretariat.*

[FR Doc. 2016-13523 Filed 6-7-16; 8:45 am]

**BILLING CODE 4165-15-P**