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 Homophilia 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. Therefore, 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.

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.

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 readetermination (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., 2nd 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


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.

• 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.”


• 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.

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 ELOCTATE (BDD–rFVIIIFc). ELOCTATE is a recombinant DNA derived, antithemophilic 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; 7,860,320; 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 effective date of the IND. However, FDA records indicate that the IND effective date was October 17, 2009. The IND became effective.
2. The date the application was initially submitted with respect to the 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 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.
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. FDA has determined that the 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:

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., 2nd 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 programs authorized by title VII 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, 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