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 PHS 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.*

Jason Bennett,

Director, Division of the Executive Secretariat.

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

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