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, if a patent is eligible for extension under these acts, the 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 the drug product ''was approved'' within the meaning of 35 U.S.C. 156. In the case of a drug recommended for controls under the Controlled Substances Act (CSA), for purposes of patent term extension the date of approval is the later of the date the application to market the drug is approved or the date of issuance of the interim final rule controlling the drug. (See 35 U.S.C. 156(i)). 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 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 BRIVIACT ORAL TABLETS (brivaracetam) under new drug application (NDA) 205836. BRIVIACT ORAL TABLETS is indicated for adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy. Subsequent to this approval, the USPTO received a patent term restoration application for BRIVIACT ORAL TABLETS (U.S. Patent No. 6,911,461) from UCB Biopharma SPRL and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated January 18, 2017, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of BRIVIACT ORAL TABLETS 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 BRIVIACT ORAL TABLETS is 4,293 days. Of this time, 3,753 days occurred during the testing phase of the regulatory review period, while 540 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 (FD&C Act) (21 U.S.C. 355(i)) became effective:* August 12, 2004. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was August 12, 2004. This IND was the first IND submitted for investigation of this active ingredient.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* November 20, 2014. FDA has verified the applicant's claim that the NDA for BRIVIACT ORAL TABLETS (NDA 205836) was initially submitted on November 20, 2014.

3. *For a drug recommended for controls under the CSA, the later of the date the NDA was approved under section 505 of the FD&C Act or the date of issuance of the interim final rule controlling the drug:* May 12, 2016. FDA has verified the applicant's claim that NDA 205836 was approved on February 18, 2016. FDA has also verified that the date of issuance of the interim final rule controlling the drug, placing BRIVIACT ORAL TABLETS (brivaracetam) in schedule V of the CSA as revised by the Improving Regulatory Transparency for New Medical Therapies Act, was May 12, 2016.

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 5 years 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, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), 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 comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (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 *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: December 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–26813 Filed 12–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Center for Advancing Translational Sciences Advisory Council.

The meeting will be open to the public as indicated below, viewing virtually by WebEx. Individuals can register to view and access the meeting by the link below.

https://nih.webex.com/nih/onstage/g.php?MTID=e56b929e2a7d82a92a5e58e040d7d103d

1. Go to ''Event Status'' on the left-hand side of page, then click ''Register''. On the registration form, enter your information and then click ''Submit'' to complete the required registration.

2. You will receive a personalized email with the live event link.

The meeting will be closed to the public in accordance with the

provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Advisory Council.

Date: January 16, 2020.

Closed: 11:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Open: 12:00 p.m. to 5:00 p.m.

Agenda: Report from the Institute Director and other staff.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, National Institutes of Health, One Democracy Plaza, Room 1072, Bethesda, MD 20892, 301–435–0809, *anna.ramseyewing@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: December 6, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–26710 Filed 12–11–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Cures Acceleration Network Review Board.

The meeting will be open to the public as indicated below, viewing virtually by WebEx. Individuals can register to view and access the meeting by the link below.

https://nih.webex.com/nih/onstage/g.php?MTID=e56b929e2a7d82a92a5e58e040d7d103d

1. Go to ''Event Status'' on the left-hand side of page, then click ''Register''. On the registration form, enter your information and then click ''Submit'' to complete the required registration.

2. You will receive a personalized email with the live event link.

Name of Committee: Cures Acceleration Network Review Board.

Date: January 16, 2020.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: Report from the Institute Director.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, National Institutes of Health, One Democracy Plaza, Room 1072, Bethesda, MD 20892, 301–435–0809 *anna.ramseyewing@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: December 6, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–26711 Filed 12–11–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Charter Renewal

It is determined that the Advisory Committee to the Deputy Director for Intramural Research, National Institutes of Health, is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), notice is hereby given that the Charter for the Advisory Committee to the Deputy Director for Intramural Research, National Institutes of Health, was renewed for an additional two-year period on August 15, 2019.

Inquiries may be directed to Claire Harris, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496–2123, or *harriscl@od.nih.gov.*

Dated: December 6, 2019.

Natasha M. Copeland,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–26709 Filed 12–11–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0063]

Agency Information Collection Activities: Petroleum Refineries in Foreign Trade Sub-Zones

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than January 13, 2020) to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP