

Staff. 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 § 10.20 (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: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**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 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 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, TURALIO (pexidartinib), indicated for treatment of adult patients with symptomatic tenosynovial giant cell tumor associated with severe morbidity or functional limitations and not amenable to improvement with surgery. Subsequent to this approval, the USPTO received patent term restoration applications for TURALIO (U.S. Patent Nos. 7,893,075; 8,461,169; and 9,169,250) from Plexxikon Inc. and the USPTO requested FDA’s assistance in determining the patents’ eligibility for patent term restoration. In a letter dated May 8, 2020, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of TURALIO 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 TURALIO is 3,637 days. Of this time, 3,394 days occurred during the testing phase of the regulatory review period, while 243 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 19, 2009. FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on August 19, 2009.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 3, 2018. FDA has verified the applicant’s claim that the new drug application (NDA) for TURALIO (NDA 211810) was initially submitted on December 3, 2018.

3. *The date the application was approved:* August 2, 2019. FDA has verified the applicant’s claim that NDA 211810 was approved on August 2, 2019.

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 1,664 days, 1,244 days or 810 days 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: June 16, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-13186 Filed 6-22-21; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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:* Center for Scientific Review Special Emphasis Panel; Small Business: SBIR/STTR Commercialization Readiness Pilot (CRP) Program.

*Date:* July 15, 2021.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Allen Richon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7892, Bethesda, MD 20892, 301-379-9351, [allen.richon@nih.hhs.gov](mailto:allen.richon@nih.hhs.gov).

*Name of Committee:* Infectious Diseases and Immunology B Integrated Review Group; HIV Coinfections and HIV Associated Cancers Study Section.

*Date:* July 15, 2021.

*Time:* 9:30 a.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Jingsheng Tuo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3196, Bethesda, MD 20892, 301-451-5953, [tuo@csr.nih.gov](mailto:tuo@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowship: Infectious Diseases and Immunology Panel C.

*Date:* July 15–16, 2021.

*Time:* 9:30 a.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Shahrooz Vahedi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 810G, Bethesda, MD 20892, (301) 496-9322, [vahedis@mail.nih.gov](mailto:vahedis@mail.nih.gov).

*Name of Committee:* Infectious Diseases and Immunology B Integrated Review Group; HIV Immunopathogenesis and Vaccine Development Study Section.

*Date:* July 15–16, 2021.

*Time:* 10:00 a.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Shiv A. Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301-443-5779, [prasads@csr.nih.gov](mailto:prasads@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Reproductive Biology.

*Date:* July 16, 2021.

*Time:* 11:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Yunshang Piao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, Bethesda, MD 20892, (301) 402-8402, [piaoy3@mail.nih.gov](mailto:piaoy3@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Infectious Diseases and Immunology Research Enhancement Review.

*Date:* July 19, 2021.

*Time:* 9:30 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, MSC 7808, Bethesda, MD 20892, 301-996-5819, [zhengli@csr.nih.gov](mailto:zhengli@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Human Complex Mental Function.

*Date:* July 19, 2021.

*Time:* 1:00 p.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Pamela Jeter, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 10J08, Bethesda, MD 20892, (301) 435-2591, [pamela.jeter@nih.gov](mailto:pamela.jeter@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in infectious diseases vaccines, therapeutics and vector biology.

*Date:* July 20, 2021.

*Time:* 9:30 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Gagan Pandya, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 3200, MSC 7808, Bethesda, MD 20892, 301-435-1167, [pandyaga@mail.nih.gov](mailto:pandyaga@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 17, 2021.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Center for Substance Abuse Treatment; Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) National Advisory Council (NAC) will meet on August 12, 2021, 1:00 p.m.–4:30 p.m. (EDT).

The meeting is open to the public and will include consideration of minutes from the SAMHSA CSAT NAC meeting of March 31, 2021; an update on CSAT activities; a discussion with SAMHSA leadership; and discussion of recovery and recovery support. Interested persons may present data, information, or views, orally or in writing, on issues pending before the Council. Written submissions should be forwarded to the contact person on or before August 6, 2021. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations must notify the contact person on or before August 6, 2021. Five minutes will be allotted for each presentation.

The meeting will be conducted via WebEx and telephone only, and registration is required to participate during this meeting. To attend virtually, or to obtain the call-in number and access code, submit written or brief oral comments, or request special accommodations for persons with disabilities, please register on-line at <http://snacregister.samhsa.gov/MeetingList.aspx>, or communicate with the CSAT National Advisory Council Designated Federal Officer; Tracy Goss (see contact information below).

Meeting information and a roster of Council members may be obtained by accessing the SAMHSA Committee website at <http://www.samhsa.gov/about-us/advisory-councils/csat-national-advisory-council> or by contacting the CSAT National Advisory Council Designated Federal Officer.

*Council Name:* SAMHSA's Center for Substance Abuse Treatment National Advisory Council.

*Date/Time/Type:* August 12, 2021, 1:00 p.m.–4:30 p.m. EDT, OPEN.

*Place:* SAMHSA, 5600 Fishers Lane, Rockville, Maryland 20857.

*Contact:* Tracy Goss, Designated Federal Officer, CSAT National Advisory Council, 5600 Fishers Lane, Rockville, Maryland 20857 (mail),