

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 POLIVY is 3,050 days. Of this time, 2,876 days occurred during the testing phase of the regulatory review period, while 174 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 4, 2011. FDA has verified the applicant's claims that the date the investigational new drug application became effective was on February 4, 2011.

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 19, 2018. FDA has verified the applicant's claim that the biologics license application (BLA) for POLIVY (BLA 761121) was initially submitted on December 19, 2018.

3. *The date the application was approved:* June 10, 2019. FDA has verified the applicant's claim that BLA 761121 was approved on June 10, 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 1,032 days, 1,127 days, or 1,445 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 23, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–13949 Filed 6–29–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2021–P–0424]

#### Medical Devices; Exemption From Premarket Notification: Powered Patient Transport, All Other Powered Patient Transport

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice announcing receipt of a petition requesting exemption from the premarket notification requirements. The document was published with an incorrect docket number. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Dan Reed, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1526, Silver Spring, MD 20993–0002, 240–402–4717.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 15, 2021 (86 FR 31722), in FR Doc. 2021–12505, on page 31722, the following correction is made:

On page 31722, in the second column, in the header of the document, and, also on page 31723, in the first column under “Instructions,” “Docket No. FDA–2021–N–0493” is corrected to read “Docket No. FDA–2021–P–0424”.

Dated: June 25, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–13967 Filed 6–29–21; 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; PAR Panel: Transgender People: Immunity, Prevention, and Treatment of HIV and STIs.

*Date:* July 26, 2021.

*Time:* 2:00 p.m. to 5:00 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:* David C. Chang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 451–0290, [changdac@mail.nih.gov](mailto:changdac@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: AIDS and AIDS-Related Applications.

*Date:* July 27, 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:* Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, (301) 496–0726, [prenticekj@mail.nih.gov](mailto:prenticekj@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; UNITE Transformative Research to Address Health Disparities and Advance Health Equity (U01).

*Date:* July 27, 2021.

*Time:* 1:00 p.m. to 5:00 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:* Bukhtiar H. Shah, DVM, Ph.D., Scientific Review Officer, Vascular and Hematology IRG, Center for Scientific

Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, (301) 806-7314, [shahb@csr.nih.gov](mailto:shahb@csr.nih.gov).

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

*Date:* July 28, 2021.

*Time:* 10:00 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:* Marci Scidmore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 301-435-1149, [marci.scidmore@nih.gov](mailto:marci.scidmore@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: HIV Molecular Virology, Cell Biology, Immune and Therapeutic-Focused Application.

*Date:* July 28, 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:* Audrey O. Lau, MPH, Ph.D., Chief Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-4088, [audrey.lau@nih.gov](mailto:audrey.lau@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Endocrinology, Metabolism, Nutrition and Reproductive Sciences.

*Date:* July 28, 2021.

*Time:* 10:00 a.m. to 5:00 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:* Elaine Sierra-Rivera, Ph.D., IRG Chief, EMNR IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6182, MSC 7892, Bethesda, MD 20892, 301-435-2514, [riverase@csr.nih.gov](mailto:riverase@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Social Sciences and Chronic and Infectious Disease Epidemiology.

*Date:* July 28, 2021.

*Time:* 11:00 a.m. to 5:00 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:* Lisa Steele, Ph.D., Scientific Review Officer, PSE IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, 301-594-6594, [steeleln@csr.nih.gov](mailto:steeleln@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Social Sciences and Chronic and Infectious Disease Epidemiology.

*Date:* July 28, 2021.

*Time:* 1:00 p.m. to 5:00 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:* Denise Wiesch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3138, MSC 7770, Bethesda, MD 20892, (301) 437-3478, [wieschd@csr.nih.gov](mailto:wieschd@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; UNITE Transformative Research to Address Health Disparities and Advance Health Equity at Minority Serving Institutions (U01).

*Date:* July 29-30, 2021.

*Time:* 10:00 a.m. to 4:00 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:* Aruna K. Behera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301-435-6809, [beheraak@csr.nih.gov](mailto:beheraak@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Mycology, Parasitology and Pathogenesis.

*Date:* July 29, 2021.

*Time:* 10:00 a.m. to 6:30 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:* Kenneth M. Izumi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3204, MSC 7808, Bethesda, MD 20892, 301-496-6980, [izumikm@csr.nih.gov](mailto:izumikm@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Endocrinology and Metabolism.

*Date:* July 29, 2021.

*Time:* 10:30 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:* Liliana N. Berti-Mattera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 6158, MSC 7890, Bethesda, MD 20892, (301) 827-7609, [liliana.ber-ti-mattera@nih.gov](mailto:liliana.ber-ti-mattera@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Program Project: Endocannabinoids as Therapeutic Targets.

*Date:* July 29, 2021.

*Time:* 1:00 p.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:* Peter B. Guthrie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC 7850, Bethesda, MD 20892, (301) 435-1239, [guthriep@csr.nih.gov](mailto:guthriep@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Innate and Adaptive Immunology.

*Date:* July 30, 2021.

*Time:* 10:00 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:* Kenneth A. Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7852, Bethesda, MD 20892, (301) 435-1166, [roebuckk@csr.nih.gov](mailto:roebuckk@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Topics in Innate and Adaptive Immunology.

*Date:* July 30, 2021.

*Time:* 10:00 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:* Neerja Kaushik-Basu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3198, MSC 7808, Bethesda, MD 20892, (301) 435-1742, [kaushikbasun@csr.nih.gov](mailto:kaushikbasun@csr.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 24, 2021.

**Melanie J. Pantoja,**

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

[FR Doc. 2021-13942 Filed 6-29-21; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Scientific Advisory Committee on Alternative Toxicological Methods; Announcement of Meeting; Request for Comments

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the next meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM). SACATM is a federally chartered external advisory group of scientists from the public and private sectors, including