

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 <https://www.regulations.gov>. Submit both copies to the Dockets Management 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.gpo.gov/fdsys/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.

**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, VABOMERE (vaborbactam and meropenem) indicated for the treatment of patients 18 years and older with complicated urinary tract infections including pyelonephritis caused by designated susceptible bacteria. Subsequent to this approval, the USPTO received a patent term restoration application for VABOMERE (U.S. Patent No. 8,680,136) from Rempex Pharmaceuticals, Inc. and the USPTO requested FDA’s assistance in determining the patent’s eligibility for patent term restoration. In a letter dated September 18, 2018, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of VABOMERE 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 VABOMERE is 1,316 days. Of this time, 1,072 days occurred during the testing phase of the regulatory review period, while 244 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:* January 23, 2014. The applicant claims February 6, 2014, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 23, 2014, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 29, 2016. FDA has verified the applicant’s claim that the new drug application (NDA) for VABOMERE (NDA 209776)

was initially submitted on December 29, 2016.

3. *The date the application was approved:* August 29, 2017. FDA has verified the applicant’s claim that NDA 209776 was approved on August 29, 2017.

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 12 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: December 5, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-26655 Filed 12-10-19; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; 30-Day Comment Request Autism Spectrum Disorder (ASD) Research Portfolio Analysis, NIMH; Correction

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

**ACTION:** Notice; correction.

**SUMMARY:** The Department of Health and Human Services, National Institutes of Health published a Notice in the **Federal Register** on December 5, 2019. That Notice requires a correction in the Supplemental information section.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: The Office of Autism Research Coordination, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9663, Room 6184, Bethesda, Maryland 20892 or can email your request, including your address to: [iaccpublicinquiries@mail.nih.gov](mailto:iaccpublicinquiries@mail.nih.gov) or [nimhprapubliccomments@mail.nih.gov](mailto:nimhprapubliccomments@mail.nih.gov) or can call Melba O. Rojas, NIMH, NIH at 301-402-0279. Formal requests for additional plans and instruments must be requested in writing.

**SUPPLEMENTARY INFORMATION:**

**Correction**

In the **Federal Register** of December 5, 2019, in FR Doc. 2019-26260, on page 66684, in the Estimated Annualized Burden Hours table; correct the "Number of projects per respondent total" column, to read: "2854".

Dated: December 5, 2019.

**Ekaterini K. Mavrophilipos,**

*Federal Register Liaison, National Institutes of Health.*

[FR Doc. 2019-26631 Filed 12-10-19; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute on Aging; Notice of Closed Meeting**

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

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 Institute on Aging Special Emphasis Panel R24/R25 Teleconference Review Committee.

*Date:* December 12, 2019.

*Time:* 1:30 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Carmen Moten, Ph.D., MPH, Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301-402-7703 [cmoten@mail.nih.gov](mailto:cmoten@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 4, 2019.

**Miguelina Perez,**

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

[FR Doc. 2019-26638 Filed 12-10-19; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting**

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

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 Institute of Allergy and Infectious Diseases Special Emphasis Panel; ZAI1-MFH-M-M, January 21-22, 2020; NIAID Clinical Trial Planning Grant (R34); NIAID Clinical Trial Cooperative Agreement (U01); NIAID SBIR Phase II Clinical Trial Implementation Agreement (U44).

*Date:* January 21-22, 2020.

*Time:* 10:00 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

*Contact Person:* Maryam Feili-Hariri, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20852, 240-669-5026, [haririmf@niaid.nih.gov](mailto:haririmf@niaid.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 5, 2019.

**Tyeshia M. Roberson,**

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

[FR Doc. 2019-26639 Filed 12-10-19; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Heart, Lung, and Blood Institute; 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 Sleep Disorders Research Advisory Board.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* Sleep Disorders Research Advisory Board.

*Date:* February 6-7, 2020.

*Time:* February 06, 2020, 1:00 p.m. to 5:00 p.m.

*Agenda:* Evaluate sleep and circadian research activities; discussion of NIH Sleep Disorders Research Plan Revision.

*Place:* National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852.

*Telephone Access:* 1-650-479-3208,

Access Code: 622 128 691.

*Virtual Access:* WebEx Link.

*Event number:* 622 128 691.

*Event password:* sdrab2020.

*Time:* February 07, 2020, 8:30 a.m. to 3:00 p.m.

*Agenda:* Coordination of inter-agency sleep research activities; discussion of NIH Sleep Disorders Research Plan Revision.

*Place:* National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852.

*Telephone Access:* 1-650-479-3208,

Access Code: 621 876 313.

*Virtual Access:* WebEx Link.

*Event number:* 621 876 313.