

the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product LAMZEDE (velmanase alfa-tycv). LAMZEDE is indicated for the treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients. Subsequent to this approval, the USPTO received a patent term restoration application for LAMZEDE (U.S. Patent No. 10,159,718) from Chiesi Farmaceutici S.p.A., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 30, 2024, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of LAMZEDE 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 LAMZEDE is 1,245 days. Of this time, 1,000 days occurred during the testing phase of the regulatory review period, while 245 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:* September 22, 2019. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 22, 2019.

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):* June 17, 2022. FDA has verified the applicant's claim that the biologics license application (BLA) for LAMZEDE (BLA 761278) was initially submitted on June 17, 2022.

3. *The date the application was approved:* February 16, 2023. FDA has verified the applicant's claim that BLA 761278 was approved on February 16, 2023.

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 745 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: May 6, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08259 Filed 5–9–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Fogarty International Center Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend in-person and or view the virtual meeting 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. The meeting can be accessed from the NIH Videocast at the following link: <https://videocast.nih.gov/>.

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: Fogarty International Center Advisory Board.

Date: June 2–3, 2025.

Closed: June 2, 2025, 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate to review and evaluate the second level of grant applications.

Address: Fogarty International Center, National Institutes of Health, Lawton Chiles International House (Stone House), 16 Center Drive, Conference Room, Bethesda, MD 20892 (In Person and Virtual Meeting).

Open: June 3, 2025, 9:00 a.m. to 3:00 p.m.

Agenda: Update and discussion of current and planned Fogarty International Center activities.

Address: Fogarty International Center, National Institutes of Health, Lawton Chiles International House (Stone House), 16 Center Drive, Conference Room, Bethesda, MD 20892 (In Person and Virtual Meeting).

Contact Person: Kristen Weymouth, Executive Secretary, Fogarty International Center, 31 Center Drive, Room B2C02, Bethesda, MD 20892, 301–495–1415, kristen.weymouth@nih.gov.

Information is also available on the Institute's/Center's home page: <https://www.fic.nih.gov/About/Advisory/Pages/default.aspx>, where an agenda and any additional information for the meeting will be posted when available.

In the interest of security, NIH has procedures at <https://www.nih.gov/about-nih/visitor-information/campusaccess-security> for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus Federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. (Catalogue of Federal Domestic Assistance Program Nos. 93.106, Minority International

Research Training Grant in the Biomedical and Behavioral Sciences; 93.154, Special International Postdoctoral Research Program in Acquired Immunodeficiency Syndrome; 93.168, International Cooperative Biodiversity Groups Program; 93.934, Fogarty International Research Collaboration Award; 93.989, Senior International Fellowship Awards Program, National Institutes of Health, HHS)

Dated: May 6, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-08242 Filed 5-9-25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 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: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurogenesis and Cell Fate Study Section.

Date: June 4–5, 2025.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Adem Can, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7850, Bethesda, MD 20892, (301) 435-1042, cana2@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel; NINDS Interdisciplinary Team Science RM1 Review (Panel A).

Date: June 5, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Bo-Shiun Chen, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892, (301) 496-9223, bo-shiun.chen@nih.gov.

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Bioengineering and Tissue Engineering for Neuroscience Study Section.

Date: June 10–11, 2025.

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

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Tina Tze-Tsang Tang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Suite 3030, Bethesda, MD 20817, (301) 435-4436, tangt@mail.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Addiction Risks and Mechanisms Study Section.

Date: June 10–11, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: 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.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Pathophysiology of Eye Disease—2 Study Section.

Date: June 11–12, 2025.

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

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Barbara Susanne Mallon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-8992, mallonb@mail.nih.gov.

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group; Cellular and Molecular Technologies Study Section.

Date: June 11–12, 2025.

Time: 9:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Tatiana V. Cohen, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, Bethesda, MD 20892, 301-455-2364, tatiana.cohen@nih.gov.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Biochemistry and Biophysics of Membranes Study Section.

Date: June 11–12, 2025.

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

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Irina V. Nesmelova, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-6496, irina.nesmelova@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Research Center in Minority Institutions (RCMI).

Date: June 11–13, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Maryline Laude, Ph.D., Scientific Review Officer, National Institute on Minority Health and Health Disparities, NIH, Gateway Building, 7201 Wisconsin Avenue, Ste. 525, MSC 5465, Bethesda, MD 20892, (301) 451-9536, mlaudesharp@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: May 6, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-08243 Filed 5-9-25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel; RFA-EB-21-001 Technology Development to Reduce Health Disparities, May 30, 2025, 09:00 a.m. to May 30, 2025, 04:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on