

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. 6200, 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 or biological 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, BYLVAY (odevixibat) indicated for the treatment of pruritis in patients 3 months of age and older with progressive familial intrahepatic cholestasis. Subsequent to this approval, the USPTO received patent term restoration applications for BYLVAY (U.S. Patent Nos. 9,694,018, 10,011,633, and 10,093,697) from Albireo Pharma, Inc. (agent for Albireo AB) and the USPTO requested FDA’s assistance in determining the patents’ eligibility for patent term restoration. In a letter dated January 18, 2024, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of BYLVAY 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 BYLVAY is 1,868 days. Of this time, 1,625 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:* June 10, 2016.

FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on June 10, 2016.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* November 20, 2020. FDA has verified the applicant’s claim that the new drug application (NDA) for BYLVAY (NDA 215498) was initially submitted on November 20, 2020.

3. *The date the application was approved:* July 20, 2021. FDA has verified the applicant’s claim that NDA 215498 was approved on July 20, 2021.

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 630 days, 679 days, or 861 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 11, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024-29966 Filed 12-17-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 1009 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 Environmental Health Sciences Special Emphasis Panel: Mechanism for Time-Sensitive Research Opportunities in Environmental Health Sciences (R21).

Date: January 15, 2025.

Time: 11:30 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709.

Meeting Format: Virtual Meeting.

Contact Person: Murali Ganesan, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training (DETR), National Institute of Environmental Health Sciences, National Institutes of Health, Keystone Building, Room 3097, Research Triangle Park, NC 27713, Phone: 984-287-4674, Email: murali.ganesan@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: December 12, 2024.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-29836 Filed 12-17-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; 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: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Early-Stage Dissemination and Implementation Research in Communication Disorders.

Date: January 16, 2025.

Time: 12:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Andrea B. Kelly, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, 6001 Executive Boulevard, Room 8351, Bethesda, MD 20892, (301) 451-6339, kellya2@nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Inner Ear Imaging RFA Review.

Date: January 30, 2025.

Time: 1:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, 6001 Executive Blvd., Rockville, MD 20852, 301-402-3587, rayk@nidcd.nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; NIDCD Institutional Research Training Opportunities Review.

Date: January 31, 2025.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Andrea B. Kelly, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, 6001 Executive Boulevard, Room 8351, Bethesda, MD 20892, (301) 451-6339, kellya2@nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; NIDCD Clinical Research Center Grant (P50) Review.

Date: February 6, 2025.

Time: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, 6001 Executive Blvd., Rockville, MD 20852, 301-402-3587, rayk@nidcd.nih.gov.

Name of Committee: National Institute on Deafness and Other Communication

Disorders Special Emphasis Panel; Chemosensory Fellowship Review Meeting.

Date: February 11, 2025.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Sonia Elena Nanesco, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Suite 8300, Bethesda, MD 20892, (301) 496-8683, sonia.nanesco@nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Hearing and Balance Fellowship Review.

Date: February 21, 2025.

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

Agenda: To review and evaluate grant applications.

Address: Hilton Garden Inn Seaworld Orlando, FL.

Meeting Format: Virtual Meeting.

Contact Person: Martin Basch, Ph.D., Scientific Review Officer, NIH/NIDCD, Scientific Review Branch, 6001 Executive Blvd., Suite 8300, Bethesda, MD 20892, (301) 496-9693, martin.basch@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: December 12, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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: National Institute on Drug Abuse Special Emphasis Panel; HEAL Initiative: Translating Research to Practice to End the Overdose Crisis.