

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, VIZIMPRO (dacomitinib) indicated for the first-line treatment of patients with metastatic non-small cell lung cancer with epidermal growth factor receptor exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test. Subsequent to this approval, the USPTO received a patent term restoration application for VIZIMPRO (U.S. Patent No. 7,772,243) from Warner-Lambert Co. LLC and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated November 29, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of VIZIMPRO 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 VIZIMPRO is 4,794 days. Of this time, 4,554 days occurred during the testing phase of the regulatory review period, while 240 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 14, 2005. The applicant claims August 15, 2005, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 14, 2005, 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 of the FD&C Act:* January 31, 2018. FDA has verified the applicant's claim that the new drug application (NDA) for

VIZIMPRO (NDA 211288) was initially submitted on January 31, 2018.

3. *The date the application was approved:* September 27, 2018. FDA has verified the applicant's claim that NDA 211288 was approved on September 27, 2018.

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 1,493 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 1, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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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 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 on Deafness and Other Communication Disorders Special Emphasis Panel; Research Opportunities for New Investigators to Promote Workforce Diversity.

*Date:* December 12, 2023.

*Time:* 12:00 p.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (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](mailto:kellya2@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. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: December 4, 2023.

**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

#### Center for Scientific Review; 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