''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. 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 or biologic 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with 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 ELFABRIO (pegunigalsidase alfa-iwxj). ELFABRIO is indicated for treatment of adults with confirmed Fabry disease. Subsequent to this approval, the USPTO received patent term restoration applications for ELFABRIO (U.S. Patent Nos. 9,194,011 and 10,280,414) from Protalix Ltd., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated January 24, 2024, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of ELFABRIO 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 ELFABRIO is 3,927 days. Of this time, 2,849 days occurred during the testing phase of the regulatory review period, while 1,078 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:* August 9, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 9, 2012.

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):* May 27, 2020. FDA has verified the applicant's claim that the biologics license application (BLA) for ELFABRIO (BLA 761161) was initially submitted on May 27, 2020.

3. *The date the application was approved:* May 9, 2023. FDA has verified the applicant's claim that BLA 761161 was approved on May 9, 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 applications for patent extension, this applicant seeks 1,271 days or 1,826 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 27, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–14536 Filed 7–1–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Order of Succession

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: General notice.

Section C–C, Order of Succession, is hereby amended as follows:

Delete in its entirety Section C–C, Order of Succession, and insert the following:

During the absence or disability of the Director, CDC, or in the event of a vacancy in that office, the first official listed below who is available shall act as Director, except that during a planned period of absence, the Director may specify a different order of succession:

1. Principal Deputy Director
2. Deputy Director for Program and Science and CDC Chief Medical Officer
3. Deputy Director for Policy, Communication, and Legislative Affairs and CDC Chief Strategy Officer
4. Director of the Office of Readiness and Response
5. Director of the National Center for Emerging and Zoonotic Infectious Diseases
6. Director of the National Center for Immunization and Respiratory Diseases

Robin Bailey,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–14500 Filed 7–1–24; 8:45 am]

BILLING CODE 4160–18–P