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 BEQVEZ (fidanacogene elaparvovec-dzkt). BEQVEZ is indicated for the treatment of adults with moderate to severe hemophilia B (congenital factor IX deficiency) who:

- Currently use factor IX prophylaxis therapy, or
- Have current or historical life-threatening hemorrhage, or
- Have repeated, serious spontaneous bleeding episodes, and,
- Do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test.

Subsequent to this approval, the USPTO received a patent term restoration application for BEQVEZ (U.S. Patent No. 10,799,566) from Children's Hospital of Philadelphia, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 12, 2025, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of BEQVEZ 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 BEQVEZ is 3,277 days. Of this time, 2,913 days occurred during the testing phase of the regulatory review period, while 364 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:* May 8, 2015. Children's Hospital of Philadelphia claims that May 10, 2015, is the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 8, 2015, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

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):* April 28, 2023. FDA has verified the applicant's claim that the biologics license application (BLA) for BEQVEZ (BLA 125786) was initially submitted on April 28, 2023.

3. *The date the application was approved:* April 25, 2024. FDA has verified the applicant's claim that BLA 125786 was approved on April 25, 2024.

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 671 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.

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2026–02387 Filed 2–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–E–1227]

Determination of Regulatory Review Period for Purposes of Patent Extension; ALFAPUMP

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ALFAPUMP and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 7, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public; you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2025–E–1227 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ALFAPUMP.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in 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.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: Jack Dan, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240–402–6940.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device, ALFAPUMP. ALFAPUMP is indicated for single patient use only in adult patients with refractory or recurrent ascites due to liver cirrhosis. It is indicated for the removal of excess peritoneal fluid from the peritoneal cavity into the bladder, where it can be eliminated through normal urination. Subsequent to this approval, the USPTO received a patent term restoration application for ALFAPUMP (U.S. Patent No. 9,149,613) from Sequana Medical NV, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 13, 2025, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of ALFAPUMP represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that the FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ALFAPUMP is 2,035 days. Of this time, 1,676 days occurred during the testing phase of the regulatory review period, while 359 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective:* May 28, 2019. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective May 28, 2019.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e):* December 28, 2023. FDA has verified the applicant's claim that the premarket approval application (PMA) for ALFAPUMP (PMA P230044) was initially submitted December 28, 2023.

3. *The date the application was approved:* December 20, 2024. FDA has verified the applicant's claim that PMA P230044 was approved on December 20, 2024.

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 1,198 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.

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2026–02384 Filed 2–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Behavioral Health Integration Evidence Based Telehealth Network Program Integration Telehealth Evidence Collection Tool, OMB No. 0906–xxxx—New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than March 9, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Behavioral Health Integration Evidence Based Telehealth Network Program Integration Telehealth Evidence Collection Tool, OMB No. 0906–xxxx—NEW.

Abstract: HRSA is requesting OMB approval of a new information collection, the Behavioral Health Integration Evidence Based Telehealth Network Program (BHI EB–TNP) Integration Telehealth Evidence Collection Tool. Under the BHI EB–TNP, HRSA administers grants in accordance with section 330I(d)(1) of the Public Health Service Act (42 U.S.C. 254c–14(d)(1)). The purpose of the BHI EP–TNP program is to integrate behavioral health services into primary care settings using telehealth technology through telehealth networks and evaluate the effectiveness of such integration. This program supports evidence-based projects that utilize telehealth technologies through telehealth networks in rural and underserved areas to: (1) improve access to integrated behavioral health services in primary care settings and (2) expand and improve the quality of health information available to health care providers by evaluating the effectiveness of integrating telebehavioral health services into primary care settings and establishing an evidence-based model that can assist health care providers.

HRSA collaborated with grantees in the development of a set of outcome measures to evaluate the effectiveness of grantees' telebehavioral services and monitor grantees' progress/effectiveness by analyzing performance reporting data. The measures address behavioral health and substance use disorder priorities and will help to assess the effectiveness of evidence-based practices with the use of telehealth for patients, providers, and payers. The data collection instrument will include 27 total data elements addressing patient encounter information.

A 60-day notice was published in the **Federal Register** on September 23, 2025, vol. 90, No. 182; pp. 45774–75. There were no public comments, but HRSA has revised the estimated burden downward to reflect fewer likely respondents and a lower average burden per response.

Need and Proposed Use of the Information: HRSA developed the BHI EB–TNP instrument with the program's four goals in mind:

(1) Improving access to the behavioral health services needed,

(2) Reducing rural and underserved population practitioner isolation,

(3) Improving health system productivity and efficiency, and

(4) Improving patient outcomes.

HRSA worked with program grantees to develop outcome measures to evaluate and monitor the progress of the grantees in each of these categories, with specific indicators to be reported annually through a performance monitoring data collection platform/website. Measures capture awardee-level and aggregate data that illustrate the impact and scope of program funding along with assessing these efforts. The measures are intended to inform HRSA's progress toward meeting program goals, specifically improving access to telebehavioral health services that support primary care providers.

Likely Respondents: BHI EB–TNP award recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.