timing requirement for when potential differences were measured—not to the requirement to control for any potential differences in the outcome before the program began.

Second, baseline equivalence standards were revised to permit use of effect sizes to establish baseline equivalence if there is a statistically significant difference on one of the required characteristics. If the baseline difference is statistically significant, reviewers then compute the effect size of the baseline difference, following the procedures specified in Appendix D of Protocol Version 2.0. If the effect size is less than 0.05 standard deviations, the baseline equivalence requirement is met. If the effect size is between 0.05 and 0.25 standard deviations, the study must control for the characteristic in their statistical model. If the effect size is greater than 0.25 standard deviations (or if an effect size cannot be computed), then the baseline equivalence requirement is not met. This revision is intended to address studies with large sample sizes where even very small differences in the magnitude of the baseline difference may be statistically significant.

2.4 Chapter 4. Assessing the Evidence of Effectiveness for a Program

Revisions were made to the program effectiveness ratings, where the criteria for the Insufficient Evidence to Assess Support rating were revised to include only cases with a single study where none of the findings are statistically significant. The criteria for Not Supported did not change but now include any cases with two or more studies that have a pattern of only null or unfavorable findings that do not meet the criteria for any other rating category. Lastly, the name of the rating category for cases with no high or moderate-quality studies identified that was formerly titled No Evidence to Assess Support has been changed to Cannot Assess Support for clarity.

2.6 Chapter 5. Assessing Cost Study Information for a Program

As the evidence base on employment programs for job seekers with low incomes continues to grow, so has the need for information about the costs of those programs and practices. Without additional information about the personnel/non-personnel resources used and the associated costs, it is impossible to provide guidance on the resources necessary for implementation and how best to allocate funding towards these efforts. Pathways to Work developed new standards for reviewing cost studies on employment and training programs designed for individuals with low incomes, with input from research and practice experts.

The draft standards cover three types of cost studies. Cost analysis provides an analysis of the comprehensive effort involved in program implementation, answering questions such as how much the program costs to implement, the per-participant cost of the program, and the feasibility of implementation given existing budget constraints and available resource inputs. Cost-effectiveness analysis compares the estimated cost of a program with an estimate of its impact on a given outcome of interest. Cost-benefit analysis compares the cost of a program with the monetized outcomes associated with that program.

The draft cost standards include two types of standards: (1) threshold standards that identify basic characteristics that cost studies must meet in order to rate the quality of the study's cost information, and (2) quality rating standards that are applied to studies that meet the threshold standards and provide additional information about how the study calculated program costs. Chapter 5 provides the threshold and quality standards for cost analyses. Studies that include a cost-effectiveness analysis and/or cost-benefit analysis will be reviewed and scored separately using the standards for each type of analysis, respectively, presented in Appendix E. A cost study rating will be assigned based on the threshold and quality rating standards. Cost studies that do not meet all the threshold standards receive a rating of Interpret cost findings with caution. Cost studies that meet all threshold standards are scored on quality rating standards on a 1 to 3 scale. A summative quality score is then generated by averaging the quality rating scores from each individual quality standard, which also ranges from 1 to 3, and rounding to the nearest tenth. A rating of Cost study meets standards with low quality will be assigned when the average score is between 1.0 and 1.5. A rating of Cost study meets standards with moderate quality will be assigned when the average score is between 1.6 and 2.5. A rating of Cost study meets standards with distinction will be assigned when the average score is between 2.6 and 3.0.

Detailed information about the proposed threshold standards for cost analyses can be found in Section 5.1 of the draft *Protocol Version 2.0.* Detailed information about the proposed cost analysis quality rating standards can be found in Section 5.2 of the draft Protocol Version 2.0. Detailed information about cost-effectiveness analysis and cost-benefit analysis threshold and quality standards can be found in Appendix E.

3.0 Timeline for the Pathways to Work To Apply New Methods and Standards

Pathways to Work proposes to apply the standards and procedures upon publication of a final Protocol Version 2.0. The public will be clearly notified on the Pathways to Work website and via appropriate dissemination channels when the final published Protocol Version 2.0 will go into effect.

4.0 Request for Information (RFI)

ACF invites comments regarding this notice on the draft ''Protocol for the Pathways to Work Evidence Clearinghouse: Methods and Standards, Version 2.0'' (*https://pathwaystowork.acf.gov/sites/default/files/2025-05/Pathways_to_Work_Methods_and_Standards_Report_V2.0.pdf*). To facilitate the review of comments submitted, please identify the chapter, section, and/or page number of the draft that your comments address. This RFI is for information and planning purposes only and should not be construed as a solicitation or as an obligation on the part of ACF or HHS. For more information about the Pathways to Work, visit: *https://pathwaystowork.acf.gov/.*

Lauren Supplee,

Deputy Assistant Secretary for Planning, Research, and Evaluation.

[FR Doc. 2025–08842 Filed 5–16–25; 8:45 am]

BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–E–3231, FDA–2023–E–3232, FDA–2023–E–3233, FDA–2023–E–3234, and FDA–2023–E–3235]

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

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 ELAHERE 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 human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by July 18, 2025. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 17, 2025. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 July 18, 2025. 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 Nos. FDA–2023–E–3231, FDA–2023–E–3232, FDA–2023–E–3233, FDA–2023–E–3234, and FDA–2023–E–3235 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ELAHERE.'' 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: Beverly Friedman or Jack Dan, 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 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 ELAHERE (mirvetuximab soravtansine-gynx). ELAHERE is indicated for the treatment of adult patients with folate receptor alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent on verification and description of clinical benefit in a confirmatory trial. Subsequent to this approval, the USPTO received patent term restoration applications for ELAHERE (U.S. Patent Nos. 8,557,966; 8,613,930; 8,624,003; 8,709,432; and 9,598,490) from ImmunoGen, Inc., and the USPTO requested FDA's assistance in determining the patents' 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 ELAHERE 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 ELAHERE is 3,867 days. Of this time, 3,635 days occurred during the testing phase of the regulatory review period, while 232 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:* April 15, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 15, 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):* March 28, 2022. FDA has verified the applicant's claim that the biologics license application (BLA) for ELAHERE (BLA 761310) was initially submitted on March 28, 2022.

3. *The date the application was approved:* November 14, 2022. FDA has verified the applicant's claim that BLA 761310 was approved on November 14, 2022.

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 1,149 days; 1,677 days; 1,733 days; 1,740 days; or 1,775 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 8, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08855 Filed 5–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0873]

Reauthorization of the Generic Drug User Fee Amendments; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is hosting a public meeting on the reauthorization of the Generic Drug User Fee Amendments (GDUFA) for fiscal years (FYs) 2028 to 2032. At the end of September 2027, new legislation will be required for FDA to continue to collect generic drug user fees for future FYs. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that before FDA begins negotiations with the regulated industry on GDUFA reauthorization, we publish a notice in the **Federal Register** requesting public input on the reauthorization; hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027 (*i.e.,* the GDUFA III Commitment Letter) (*https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iii-reauthorization*); provide a period of 30 days after the public meeting to obtain written comments from the public; and publish the comments on FDA's website. FDA invites public comment on the GDUFA program and suggestions regarding the features FDA should propose for the next GDUFA program cycle. These comments will be published and available on FDA's website.

DATES: The hybrid public meeting will be held in person and virtually on July 11, 2025, from 9 a.m. to 2 p.m. Either electronic or written comments on this public meeting must be submitted by August 11, 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held in person at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room, Silver Spring, MD 20993–0002 and virtually using the Microsoft Teams platform. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.*

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 on August 11, 2025. 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