

LIMFLOW SYSTEM is indicated for patients who have chronic limb-threatening ischemia with no suitable endovascular or surgical revascularization options and are at risk of major amputation. Subsequent to this approval, the USPTO received patent term restoration applications for LIMFLOW SYSTEM (U.S. Patent Nos. 9,326,792; 9,532,803; and 10,136,987) from LimFlow GmbH, and the USPTO requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated June 27, 2025, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of LIMFLOW SYSTEM 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 LIMFLOW SYSTEM is 2,337 days. Of this time, 2,022 days occurred during the testing phase of the regulatory review period, while 315 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:* April 20, 2017. FDA has verified the applicant's claim that the date the investigational device exemption required under section 520(g) of the act for human tests to begin became effective April 20, 2017.

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):* November 1, 2022. The applicant claims October 31, 2022, as the date the premarket approval application (PMA) for LIMFLOW SYSTEM (PMA P220025) was initially submitted. However, FDA records indicate that PMA P220025 was submitted on November 1, 2022.

3. *The date the application was approved:* September 11, 2023. FDA has verified the applicant's claim that PMA P220025 was approved on September 11, 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 application for patent extension,

this applicant seeks 1,033; or 1,327 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–03855 Filed 2–25–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–E–3572]

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

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 TEVIMBRA 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 April 27, 2026. 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 August 25, 2026. 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 April 27, 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–2024–E–3572 for “Determination of Regulatory Review Period for Purposes of Patent Extension; TEVIMBRA.” 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 (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 TEVIMBRA (tislezumab-jsgr). TEVIMBRA is indicated for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor. Subsequent to this approval, the USPTO received a patent term restoration application for TEVIMBRA (U.S. Patent No. 8,735,553) from BeiGene Switzerland GmbH, and the USPTO requested FDA’s assistance in determining this patent’s eligibility for

patent term restoration. In a letter dated August 26, 2025, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of TEVIMBRA 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 TEVIMBRA is 2,997 days. Of this time, 2,021 days occurred during the testing phase of the regulatory review period, while 976 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:* December 31, 2015. FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on December 31, 2015

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):* July 12, 2021. The applicant claims July 10, 2021, as the date the biologics license application (BLA) for TEVIMBRA (BLA 761232) was initially submitted. However, FDA records indicate that BLA 761232 was submitted on July 12, 2021.

3. *The date the application was approved:* March 13, 2024. The applicant claims March 14, 2024, as the date the BLA for TEVIMBRA (BLA 761232) was approved. However, FDA records indicate that BLA 761232 was approved on March 13, 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 1,987 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–03851 Filed 2–25–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Request for Information: 340B Rebate Model Pilot Program Extension

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

ACTION: Notice of extension for the comment period for the Request for Information: 340B Rebate Model Pilot Program (91 FR 7287).

SUMMARY: The Health Resources and Services Administration (HRSA) is extending the comment period for Request for Information: 340B Rebate Model Pilot Program from 30 days to 60 days. The change will provide stakeholders additional time to submit meaningful comments for HRSA's review in evaluating operational, financial, and potential impacts on access to drugs for patients under a rebate model.

DATES: Comments on this notice should be received no later than April 20, 2026.

FOR FURTHER INFORMATION CONTACT: Chantelle Britton, Director, Office of Pharmacy Affairs (OPA), Office of Special Health Initiatives, HRSA, 5600 Fishers Lane, Mail Stop 10W29, Rockville, MD 20857; email: 340Bpricing@hrsa.gov; telephone: 301–594–4353.

SUPPLEMENTARY INFORMATION: None.

Thomas J. Engels,

Administrator.

[FR Doc. 2026–03838 Filed 2–25–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906–NEW

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than April 27, 2026.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed collection or to obtain a copy of the information collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906–XXXX.

Abstract: HRSA's Office of Pharmacy Affairs (OPA) is considering a potential 340B Rebate Model Pilot Program as a voluntary mechanism for qualifying drug manufacturers to effectuate the 340B ceiling price on select drugs to covered entities, and is requesting

information from 340B stakeholders and others as described in a Request for Information (91 FR, 7287) issued on February 17, 2026.¹ This ICR includes the collection of proposed rebate model plans from qualifying drug manufacturers, the collection of reports from drug manufacturers approved for participation to allow OPA to evaluate the Pilot Program and enhance 340B Program integrity and compliance monitoring, and the collection of data submitted by covered entities to participating drug manufacturers to request a rebate in connection with a potential 340B Rebate Model Pilot Program.

Need and Proposed Use of the Information: This new proposed information collection request will replace an emergency clearance ICR, OMB No: 0906–0111 (Reference No: 202508–0906–002),² which HRSA discontinued. The scope of the potential 340B Rebate Model Pilot Program will be limited to manufacturers with Medicare Drug Price Negotiation Program Agreements with the Centers for Medicare & Medicaid Services' for the initial price applicability years 2026 and 2027.³ This information collection request includes the collection of proposed rebate model plans from qualifying drug manufacturers, the ongoing collection of sales data from drug manufacturers to allow OPA to evaluate the pilot program and enhance 340B Program integrity and compliance monitoring, and the collection of data submitted by covered entities to manufacturers to request a rebate in connection with a potential 340B Rebate Model Pilot Program.

Collection of Drug Manufacturer Applications: OPA anticipates evaluating and approving manufacturer plans for participation in a potential 340B Rebate Model Pilot Program based on requirements published by OPA in future guidance.

Collection of Reporting Data from Manufacturers: In a potential 340B Rebate Model Pilot Program, manufacturers will be required to

¹ *Request for Information* (91 FR, 7287) issued on February 17, 2026, available at <https://www.federalregister.gov/documents/2026/02/17/2026-03042/request-for-information-340b-rebate-model-pilot-program>.

² 340B Rebate Model Pilot Program Application, Implementation, and Evaluation (0906–0111) available at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202508-0906-002.

³ The Fact Sheets for Negotiated Prices for Applicability Years 2026 and 2027 includes the list of Primary Manufacturers with selected drugs, available at <https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf> and <https://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf> respectively.