

pathways, environmental fate, and risks associated with indoor and ambient exposures.

2. Mid-2026 Chemicals Under Consideration

- **1,2-Dichloropropane (1,2-DCP):** 1,2-DCP is a chlorinated solvent used in consumer and industrial cleaning, chemical synthesis, and as an intermediate. EPA designated it as a High-Priority substance due to concerns for inhalation and dermal exposure and potential carcinogenicity. EPA's draft risk evaluation will assess general population, occupational and consumer exposures, environmental releases, fate and transport, and human health and environmental hazards.

- **1,1,2-Trichloroethane (1,1,2-TCA):** 1,1,2-TCA is used as a solvent and chemical intermediate. EPA designated it as a High-Priority Substance for risk evaluation under TSCA in 2019. Its evaluation will address general population, occupational and consumer exposures via inhalation and dermal exposure pathways; environmental releases from industrial use; and potential human and environmental health hazards including systemic toxicity and carcinogenicity.

- **trans-1,2-Dichloroethylene (trans-DCE):** trans-DCE is a highly flammable, colorless liquid. It is a synthetic chemical with no known natural sources, and it is used as a solvent in processing and in formulations for cleaning and degreasing, among other uses. EPA designated it as a High-Priority Substance for risk evaluation under TSCA in 2019. EPA's risk evaluation will address potentially exposed or susceptible subpopulations (PESS), environmental and human health hazards, and exposures and impacts across conditions of use.

- **Ethylene Dibromide (EDB):** EDB is primarily used in chemical synthesis and as a fuel additive. It was historically used as a fumigant. EDB has known toxicity and potential carcinogenic effects. EPA designated it as a High-Priority Substance under TSCA. EPA's draft evaluation will consider inhalation and dermal exposures during manufacturing, processing and use, environmental fate, ecological effects, and health hazards associated with occupational, consumer, and general population exposures.

- **Tetrabromobisphenol A (TBBPA):** TBBPA is a brominated flame retardant used in printed circuit boards, resins, and polymer systems. EPA designated it as a High-Priority Substance due to potential ecological hazards, persistence, and possible endocrine-related effects. The risk evaluation will

address aquatic and sediment exposure pathways, environmental fate, bioaccumulation, and human health risks associated with occupational and consumer uses.

- **Triphenyl Phosphate (TPP):** TPP is used as a flame retardant and plasticizer in polymers, electronics, and consumer products. EPA designated it as a High-Priority Substance under TSCA. TPP may be released to air, water, or dust during use and disposal. EPA's risk evaluation will consider exposure to workers and consumers, environmental fate, ecological effects, and potential risks across conditions of use.

(Authority: 15 U.S.C. 2625(o); 5 U.S.C. 10.)

Dated: December 30, 2025.

Nancy B. Beck,

*Principal Deputy Assistant Administrator,
Office of Chemical Safety and Pollution
Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-E-1289]

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

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 AUGTYRO 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 drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by March 6, 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 July 6, 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 March 6, 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-1289 for "Determination of Regulatory Review Period for Purposes of Patent Extension; AUGTYRO." 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, 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 biological 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 drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an 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, AUGTYRO (reprotrectinib), is indicated for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC). Subsequent to this approval, the USPTO received a patent term restoration application for AUGTYRO (U.S. Patent No. 9,714,258) from Turning Point Therapeutics, Inc. and the USPTO requested FDA’s assistance in determining the patent’s eligibility for patent term restoration. In a letter dated June 27, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of AUGTYRO 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 AUGTYRO is 2,574 days. Of this time, 2,340 days occurred during the testing phase of the regulatory review period, while 234 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:* October 30, 2016. The applicant claims October 29, 2016, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was, October 30, 2016, 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:* March 27, 2023. FDA has verified the applicant’s claim that the new drug application (NDA) for AUGTYRO (NDA 218213) was initially submitted on March 27, 2023.

3. *The date the application was approved:* November 15, 2023. FDA has verified the applicant’s claim that NDA 218213 was approved on November 15, 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(s) for patent extension, this applicant seeks 1,027 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. 2025-24270 Filed 1-2-26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2023-E-3139; FDA-2023-E-3189; FDA-2023-E-3190; FDA-2023-E-3195]

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

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 BRENZAVVY and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications 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 drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by March 6, 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 July 6, 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 March 6, 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.

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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>.

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Instructions: All submissions received must include the Docket Nos. FDA-2023-E-3139; FDA-2023-E-3189; FDA-2023-E-3190; and FDA-2023-E-3195 for “Determination of Regulatory Review Period for Purposes of Patent Extension; BRENZAVVY.” 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.

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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>.

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