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, CRENESSITY (crinecerfont). CRENESSITY is indicated as adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia. Subsequent to this approval, the USPTO received patent term restoration applications for CRENESSITY (U.S. Patent Nos. 10,905,690; 11,311,544; and 11,730,739) from Neurocrine Biosciences, Inc. and the USPTO requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated October 8, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of CRENESSITY 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 CRENESSITY is 2,884 days. Of this time, 2,655 days occurred during the testing phase of the regulatory review period, while 229 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:* January 22, 2017. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 22, 2017.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* April 29, 2024. FDA has verified the applicant's claim that the new drug application (NDA) for CRENESSITY (NDA 218808) was initially submitted on April 29, 2024.

3. *The date the application was approved:* December 13, 2024. FDA has verified the applicant's claim that NDA 218808 was approved on December 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 355, 596, or 820 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. 2026–02973 Filed 2–12–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2025–E–0361 and FDA–2025–E–0362]

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

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 AUCATZYL 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 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 14, 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 12, 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 14, 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 Nos. FDA–2025–E–0361 and FDA–2025–E–0362 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; AUCATZYL.'' 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 AUCATZYL (obecabtagene autoleucel). AUCATZYL is indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia. Subsequent to this approval, the USPTO received patent term restoration applications for AUCATZYL (U.S. Patent Nos. 10,457,730 and 11,578,126) from Autolus Limited, and the USPTO requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated September 23, 2025, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of AUCATZYL 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 AUCATZYL is 1,671 days. Of this time, 1,313 days occurred during the testing phase of the regulatory review period, while 358 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 14, 2020. FDA has verified the applicant's claim that the date the investigational new drug

application became effective was on April 14, 2020.

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):* November 17, 2023. FDA has verified the applicant's claim that the biologics license application (BLA) for AUCATZYL (BLA 125813) was initially submitted on November 17, 2023.

3. *The date the application was approved:* November 8, 2024. FDA has verified the applicant's claim that BLA 125813 was approved on November 8, 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 496 or 705 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. 2026–02972 Filed 2–12–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: In Vivo Manufactured Anti-CD19 Chimeric Antigen Receptor (CAR) Products for the Treatment or Prevention of B Cell Mediated Autoimmune Diseases

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the patents and patent applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice to Kyverna Therapeutics, Inc. (''Kyverna''), a company located in Emeryville, California, the United States of America.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before March 2, 2026 will be considered.

ADDRESSES: Inquiries and comments relating to the contemplated Exclusive Patent License should be directed to: Andrew Burke, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)–276–5484; Email: *andy.burke@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. U.S. Provisional Patent Application 62/006,313 (HHS Reference E–042–2014–0–US–01), filed 2 June 2014;

2. PCT Application PCT/US2015/033473 (HHS Reference E–042–2014–0–PCT–02), filed 1 June 2015;

3. Australian Patent 2015270912 (HHS Reference E–042–2014–0–AU–03), issued 17 December 2020;

4. Canadian Patent Application 2951045 (HHS Reference E–042–2014–0–CA–04), filed 1 June 2015;

5. Chinese Patent ZL201580033802.5 (HHS Reference E–042–2014–0–CN–05), issued 31 August 2021;

6. European Patent 3149044 (HHS Reference E–042–2014–0–EP–06), issued 21 October 2020 and validated in the following jurisdictions:

a. Germany (HHS Reference E–042–2014–0–DE–19);

b. Spain (HHS Reference E–042–2014–0–ES–20);

c. France (HHS Reference E–042–2014–0–FR–21);

d. The United Kingdom (HHS Reference E–042–2014–0–GB–22);

e. Italy (HHS Reference E–042–2014–0–IT–23); and

f. Ireland (HHS Reference E–042–2014–0–IE–24);

7. Israeli Patent 249305 (HHS Reference E–042–2014–0–IL–07), issued 1 October 2021;

8. Indian Patent 406961 (HHS Reference E–042–2014–0–IN–08), filed 19 May 2022;

9. Japanese Patent 6797693 (HHS Reference E–042–2014–0–JP–09), issued 20 November 2020;

10. South Korean Patent 2016–7036828 (HHS Reference E–042–2014–0–KR–10), issued 20 May 2024;

11. Mexican Patent 383150 (HHS Reference E–042–2014–0–MX–11), issued 3 June 2021;

12. New Zealand Patent 727167 (HHS Reference E–042–2014–0–NZ–12), issued 8 October 2024;

13. Saudi Arabian Patent 8651 (HHS Reference E–042–2014–0–SA–13), issued 15 September 2021;

14. Singapore Patent 11201609960Q (HHS Reference E–042–2014–0–SG–14), issued 28 September 2021;

15. United States Patent 10,287,350 (HHS Reference E–042–2014–0–US–15), issued 14 May 2019;

16. Hong Kong Patent HK 1234420 (HHS Reference E–042–2014–0–HK–16), issued 4 June 2021;

17. United States Patent 11,236,161 (HHS Reference E–042–2014–0–US–17), issued 1 February 2022;

18. New Zealand Patent 764530 (HHS Reference E–042–2014–0–NZ–18), issued 8 October 2024;

19. European Patent Application 20197459.9 (HHS Reference E–042–2014–0–EP–25), filed 22 September 2020;

20. Australian Patent 2020267211 (HHS Reference E–042–2014–0–AU–26), issued 15 August 2024;

21. Japanese Patent 7004470 (HHS Reference E–042–2014–0–JP–27), issued 6 January 2022;

22. Mexican Patent Application MX/a/2021/006239 (HHS Reference E–042–2014–0–MX–28), filed 27 May 2021;

23. Israeli Patent 283423 (HHS Reference E–042–2014–0–IL–29), issued 2 July 2022;

24. Hong Kong Patent Application 42021038427.7 (HHS Reference E–042–2014–0–HK–30), filed 8 September 2021;

25. United States Patent Application 17/557,845 (HHS Reference E–042–2014–0–US–31), filed 21 December 2021;