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 IMAAVY (nipocalimab-aahu). IMAAVY is indicated for the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or antimuscle-specific tyrosine kinase (MuSK) antibody positive. Subsequent to this approval, the USPTO received a patent term restoration application for IMAAVY (U.S. Patent No. 10,676,526) from Momenta Pharmaceuticals, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 19, 2025, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of IMAAVY 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 IMAAVY is 2,453 days. Of this time, 2,209 days occurred during the testing phase of the regulatory review period, while 244 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:* August 13, 2018. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 13, 2018.

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):* August 29, 2024. FDA has verified the applicant's claim that the biologics license application (BLA) for IMAAVY (BLA 761430) was initially submitted on August 29, 2024.

3. *The date the application was approved:* April 29, 2025. FDA has verified the applicant's claim that BLA 761430 was approved on April 29, 2025.

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 1,007 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. 2026–01575 Filed 1–26–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–2125 and FDA–2024–E–2145]

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

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 EXBLIFEP 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 30, 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 27, 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 30, 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–2024–E–2125 and FDA–2024–E–2145 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; EXBLIFEP.'' 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 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, EXBLIFEP (cefepime hydrochloride/enmetazobactam), indicated for the treatment of patients 18 years of age and older with complicated urinary tract infections (cUTI) including pyelonephritis, caused by the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae,Pseudomonas aeruginosa, Proteus mirabilis,* and *Enterobacter cloacae* complex. Subsequent to this approval, the USPTO received patent term restoration applications for EXBLIFEP (U.S. Patent Nos. 7,687,488; and 11,124,526) from Allecra Therapeutics GmbH and the USPTO requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated August 12, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of EXBLIFEP 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 EXBLIFEP is 2,374 days. Of this time, 2,128 days occurred during the testing phase of the regulatory review period, while 246 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:* August 25, 2017. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 25, 2017.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* June 22, 2023. FDA has verified the applicant's claim that the new drug application (NDA) for EXBLIFEP (NDA 216165) was initially submitted on June 22, 2023.

3. *The date the application was approved:* February 22, 2024. FDA has verified the applicant's claim that NDA 216165 was approved on February 22, 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 574 days or 1,309 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. 2026–01587 Filed 1–26–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Rescission of Guidance to Nation's Retail Pharmacies: Obligations Under Federal Civil Rights Laws To Ensure Nondiscriminatory Access to Health Care at Pharmacies (Issued September 29, 2023)

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, Department of Health and Human Services.

ACTION: Notice; rescission of guidance.

SUMMARY: The U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR) hereby rescinds ''Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Nondiscriminatory Access to Health Care at Pharmacies,'' issued on September 29, 2023 (2023 Guidance) as revised guidance to ''Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services,'' originally issued on July 13, 2022 (2022 Guidance). This recission is effective upon publication.

DATES: This action is effective January 27, 2026.

FOR FURTHER INFORMATION CONTACT: David Christensen, Supervisory Policy Advisor, HHS Office for Civil Rights, (202) 741–8460 or (800) 537–7697 (TDD), or by email at *Conscience@hhs.gov*

SUPPLEMENTARY INFORMATION:

I. Background

In light of the stated policy in Executive Order (''E.O.'') 14182, ''Enforcing the Hyde Amendment,'' to end the forced use of Federal taxpayer dollars to fund or promote elective abortion, and the direction under E.O. 14219, ''Ensuring Lawful Governance and Implementing the President's 'Department Of Government Efficiency' Deregulatory Initiative,'' to rescind or modify ''regulations that are based on anything other than the best reading of the underlying statutory authority or prohibition,'' [1] The U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR) hereby rescinds ''Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Nondiscriminatory Access to Health Care at Pharmacies.''

On July 13, 2022, OCR issued ''Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services,'' (2022 Guidance) to purportedly remind roughly 60,000 retail pharmacies in the United States that they must comply with civil rights laws such as Section 1557 of the Affordable Care Act (Section 1557), 42 U.S.C. 18116,[2] which prohibits discrimination on the basis of sex, among other bases, and Section 504 of the Rehabilitation Act of 1973 (Section 504), 42 U.S.C. 794,[3] which prohibits discrimination on the basis of disability. The 2022 Guidance stated that pharmacies may not discriminate against pharmacy customers based on sex and disability, which it contended might be the case if pharmacists did not stock or dispense various drugs. It also asserted the application of federal civil rights laws to pharmacies in various ways. First, according to the 2022 Guidance, disparities in maternal health for minority women would be exacerbated by the Supreme Court decision in *Dobbs* v. *Jackson Women's Health Organization*.[4] Second, the 2022 Guidance also stated that OCR is responsible for protecting the ''rights of women and pregnant people'' (sic) in their ability to access health care that is free from discrimination, including nondiscriminatory access to ''reproductive health care,'' including prescription medication from their pharmacy. Third, the 2022 Guidance specified examples of what may constitute discrimination by a pharmacist, including failure to stock or fill prescriptions for drugs that may be used as contraceptives and abortion, if refusal to distribute the drugs would deny individuals with certain conditions their use. A few examples discussed the drugs ''mifepristone,'' ''misoprostol,'' and ''methotrexate,'' all of which can cause an abortion, but the latter two of which have FDA-approved uses for non-abortion purposes. Mifepristone and misoprostol are part of the FDA-approved abortion regimen, while methotrexate can end an ectopic pregnancy.

The 2022 Guidance was challenged in district court by the State of Texas and individual providers who contended that it required pharmacies to dispense abortion-inducing drugs as a condition of receiving federal financial assistance in violation of federal law. OCR, in response to this litigation, issued ''Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Nondiscriminatory Access to Health Care at Pharmacies'' (September 29, 2023) (2023 Guidance), which revised the 2022 Guidance in several ways. The 2023 Guidance removed the mention of ''mifepristone,'' removed the reference to the claim that the *Dobbs* decision would exacerbate ''inequities and disparities for women,'' and added language stating the guidance does not ''require pharmacies to fill prescriptions for medication for the purpose of abortion'' or imply any obligation for pharmacies to fill prescriptions in violation of state laws, including those that restrict abortion. In addition, the

[1] Pursuant to Section 6 of E.O. 14219, the term ''regulation'' includes the term ''guidance document'' as defined in E.O. 13422 of January 18, 2007, Further Amendment to Executive Order 12866 on Regulatory Planning and Review ('''Guidance document' means an agency statement of general applicability and future effect, other than a regulatory action, that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue.'' E.O. 13422, Sec. 3(g) (Jan. 18, 2007).).

[2] Section 1557's implementing regulation, 45 CFR part 92, prohibits recipients of federal financial assistance from excluding an individual from participation in, denying an individual the benefits of, or otherwise subjecting an individual to discrimination on the basis of sex and disability, among other bases.

[3] Section 504's implementing regulation, 45 CFR part 84, prohibits recipients of federal financial assistance from discriminating in their programs or activities on the basis of disability.

[4] 597 U.S. 215 (2022).