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 ENFLONSIA (clesrovimab-cfor). ENFLONSIA is indicated for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season. Subsequent to this approval, the USPTO received a patent term restoration application for ENFLONSIA (U.S. Patent No. 9,963,500) from Merck Sharp & Dohme LLC, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 15, 2025, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of ENFLONSIA 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 ENFLONSIA is 2,956 days. Of this time, 2,713 days occurred during the testing phase of the regulatory review period, while 243 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:* May 8, 2017. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 8, 2017.

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):* October 10, 2024. FDA has verified the applicant's claim that the biologics license application (BLA) for ENFLONSIA (BLA 761432) was initially submitted on October 10, 2024.

3. *The date the application was approved:* June 9, 2025. FDA has verified the applicant's claim that BLA 761432 was approved on June 9, 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 955 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. 2026–06479 Filed 4–2–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–E–0372]

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

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 ZIIHERA 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 June 2, 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 September 30, 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 June 2, 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–2025–E–0372 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ZIIHERA.'' 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: Patrick Clouser, Office of the Commissioner, Food and Drug Administration, 12420 Parklawn Drive, Rockville, MD 20852, 240–402–5276.

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 ZIIHERA (zanidatamab-hrii). ZIIHERA is indicated for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC), as detected by an FDA-approved test. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Subsequent to this approval, the USPTO received a patent term restoration application for ZIIHERA (U.S. Patent No. 10,000,576) from Zymeworks BC Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 8, 2025, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of ZIIHERA 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 ZIIHERA is 3,038 days. Of this time, 2,801 days occurred during the testing phase of the regulatory review period, while 237 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:* July 29, 2016. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 29, 2016.

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 29, 2024. The applicant claims December 15, 2023, as the date the biologics license application (BLA) for ZIIHERA (BLA 761416) was initially submitted. However, FDA records indicate that BLA 761416 was submitted on March 29, 2024.

3. *The date the application was approved:* November 20, 2024. The applicant claims November 21, 2024, as the date the biologics license application was approved. However, FDA records indicate that BLA 761416 was approved on November 20, 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 1,346 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. 2026–06476 Filed 4–2–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) is issuing this notice to revise its Statement of Organization, Functions, and Delegations of Authority for the Office of the Secretary (OS). This reorganization removes the Office of the Chief Information Officer (OCIO) from the organizational description for the Office of the Assistant Secretary for Administration (ASA), and establishes the OCIO as a stand-alone organization that reports directly to the Secretary and Deputy Secretary. These changes supersede the OCIO-related organizational language contained in the notice published at 74 FR 57747 (November 9, 2009) (document number E9–26963) and any subsequent amendments, as well as corresponding OCIO references in the Assistant Secretary for Administration **Federal Register** notice published at 90 FR 3655 (January 10, 2025) (document number 2025–00382).

DATES: This reorganization is effective upon date of publication of this notice in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Bobby D. Flanders, Jr., Office of the Chief Information Officer, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, telephone: 202–969–3622, email: *bobby.flanders@hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Office of the Assistant Secretary for Administration (ASA)

Under the heading ''Office of the Assistant Secretary for Administration'' in the **Federal Register** notice published at 90 FR 3655 (January 10, 2025) (document number 2025–00382), all references to the ''Office of the Chief Information Officer'' (OCIO), including its subcomponents, functions, and delegations, are removed.

Any functions, responsibilities, or delegations previously assigned to OCIO under the ASA are reassigned to the Office of the Chief Information Officer established in Section II of this notice.

II. Office of the Chief Information Officer (OCIO)

A. Mission

The Office of the Chief Information Officer (OCIO) is established within the Office of the Secretary as an independent organization that reports directly to the Secretary and Deputy Secretary. OCIO supports the HHS mission by leading the development, modernization, and secure operation of enterprise information technology across the Department; setting strategy and governance for IT, data, cybersecurity, and artificial intelligence; and delivering shared technology capabilities that enable HHS programs to focus on their unique missions while providing better, more efficient, and more affordable services to the American people.

B. Organization

The Office of the Chief Information Officer (OCIO) is led by the Chief Information Officer (CIO). The Deputy Chief Information Officer (DCIO), the Chief Technology Officer (CTO), who leads the Office of the Chief Technology Officer (OCTO), and the Chief Artificial Intelligence Officer (CAIO), who leads the Office of the Chief Artificial Intelligence Officer (OCAIO), report directly to the CIO.

The OCIO consists of the following components:

1. Immediate Office (AO1)
2. Office of Information Security (AO2)
3. Office of Operations (AO3)
4. Office of HR IT Modernization (AO4)
5. Office of the Chief Data Officer (AO5)
6. Office of the Chief Technology Officer (AO6)
7. Office of the Chief Artificial Intelligence Officer (AO7)

The Executive Officer (XO), who leads the Immediate Office (IO); the Chief Data Officer (CDO), who leads the Office of the Chief Data Officer (OCDO); the Chief Information Security Officer (CISO) and Executive Director, Office of Information Security (OIS), who leads OIS; the Executive Director, Operations (Ops), who leads Ops; and the Executive Director, HR IT Modernization, who leads HRITMod, all report to the DCIO.

C. Functions

1. Immediate Office (AO1)

The Immediate Office (IO), led by the Executive Officer (XO), provides executive leadership, strategic planning, and overall management of OCIO. The IO leads enterprise-wide IT governance; coordinates with HHS Operating Divisions and Staff Divisions; and manages budget formulation and