

RAPS Format from Medicare Advantage Organizations for Risk Adjusted Payments; *Use*: Section 1853 of the Social Security Act, hereafter referred to as “the Act,” requires CMS to make advance monthly payments to a Medicare Advantage (MA) organization for each beneficiary enrolled in an MA plan offered by the organization for coverage of Medicare Part A and Part B benefits. Section 1853(a)(1)(C) of the Act requires CMS to adjust the monthly payment amount for each enrollee to take into account the health status of MA plan enrollees. Under the CMS Hierarchical Condition Category (HCC) risk adjustment payment methodology, CMS determines risk scores for MA enrollees for a year and uses the appropriate enrollee risk score to adjust the monthly payment amount.

CMS used RAPS data, in combination with encounter data and Fee-For-Service (FFS) data, to develop the diagnosis-based portion of the risk scores for risk adjusted payment to MA organizations, PACE organizations, and MMPs. *Form Number*: CMS–10062 (OMB control number: 0938–0878); *Frequency*: Quarterly; *Affected Public*: Private Sector, Business or other for-profits and Not-for-profits institutions; *Number of Respondents*: 182; *Number of Responses*: 29,729,927; *Total Annual Hours*: 990,007. (For policy questions regarding this collection contact Deven Gosalia at 410–786–8264.)

**2. Type of Information Collection Request**: Reinstatement without change of a previously approved collection; *Title of Information Collection*: Data Request and Attestation for PDP Sponsors; *Use*: Section 50354 of the BBA requires that the Secretary establish a process for PDP sponsors to submit a request for standardized extracts of claims data for their enrollees. In addition, Section 50354 of the BBA provides for a number of purposes and limitation for the use of the claims data and also permits the Secretary to establish other limitations necessary to protect the identity of individuals entitled to or enrolled in Medicare, and to protect the security of personal health information.

This information collection request allows a PDP sponsor to submit a request to CMS for claims data for its enrollees and to attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data that are listed in 42 CFR 423.153(g)(3) and After requesting claims data for its enrollees and attesting to the permitted uses and limitations of Medicare claims data, PDP sponsors are required to complete some basic on-boarding activities before gaining access to

Medicare claims data using the Part A and B Claims Data to Part D Sponsors (AB2D) API. *Form Number*: CMS–10691 (OMB control number: 0938–1371); *Frequency*: Annually; *Affected Public*: Private Sector, Business or other for profits, and Not for profits institutions; *Number of Respondents*: 200; *Total Annual Responses*: 200; *Total Annual Hours*: 36. (For questions regarding this collection contact Andrew Harnish at 410–786–8246 or [andrew.harnish1@cms.hhs.gov](mailto:andrew.harnish1@cms.hhs.gov)).

**William N. Parham, III,**

*Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.*

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**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2025–E–0500]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; TRYNGOLZA

**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 TRYNGOLZA 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 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–2025–E–0500 for “Determination of Regulatory Review Period for Purposes of Patent Extension; TRYNGOLZA.” 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, TRYNGOLZA (olezarsen sodium). TRYNGOLZA is indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome. Subsequent to this approval, the USPTO received a patent term restoration application for TRYNGOLZA (U.S. Patent No. 9,163,239) from Ionis Pharmaceuticals, Inc. and the USPTO requested FDA’s assistance in determining the patent’s 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 TRYNGOLZA 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 TRYNGOLZA is 2,534 days. Of this time, 2,289 days occurred during the testing phase of the regulatory review period, while 245 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 13, 2018. FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on January 13, 2018.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* April 19, 2024. FDA has verified the applicant’s claim that the new drug application (NDA) for TRYNGOLZA (NDA 218614) was initially submitted on April 19, 2024.

3. *The date the application was approved:* December 19, 2024. FDA has verified the applicant’s claim that NDA 218614 was approved on December 19, 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 1,390 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.*

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