

and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. Type of Information Collection
Request: Revision of a currently approved collection; *Title of Information Collection:* HEDIS Data Collection for Medicare Advantage; *Use:* Sections 422.152 and 422.516 of Volume 42 of the Code of Federal Regulations (CFR) specify that MAOs must submit quality performance measures as specified by the Secretary of the Department of Health and Human Services and by CMS. These quality performance measures include HEDIS®. HEDIS® data are used in the Medicare Part C Star Ratings which are used to determine Quality Bonus Payments to Medicare Advantage contracts.

CMS requires MAOs, § 1876 cost contracts, and Medicare Medicaid Plans (MMPs or demonstrations) to submit HEDIS® data on an annual basis to (1) assess care that is provided to Medicare beneficiaries and (2) to provide information to Medicare beneficiaries to make more informed decisions when choosing a health plan.

The HEDIS® data collection supports the CMS strategic goals of advancing health equity and improving health outcomes for Medicare beneficiaries. The HEDIS® measures are part of the Medicare Part C Star Ratings as described at §§ 422.160, 422.162, 422.164, and 422.166. CMS publishes the Medicare Part C Star Ratings each year to: (1) incentivize quality improvement in Medicare Advantage (MA); and (2) assist beneficiaries in finding the best plan for them. The Star Ratings are used to determine MA Quality Bonus Payments. *Form Number:* CMS-10219 (OMB control number: 0938-1028); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits and Not-for-profits institutions; *Number of Respondents:* 808; *Total Annual Responses:* 808; *Total Annual Hours:* 258,560. (For policy

questions regarding this collection contact Lori Luria at Lori.Luria@cms.hhs.gov).

2. Type of Information Collection
Request: Extension of a currently approved collection; *Title of Information Collection:* Establishment of an Exchange by a State and Qualified Health Plans; *Use:* Section 1311(d) of the Affordable Care Act requires an Exchange to be a governmental agency or nonprofit entity established by a State; requires an Exchange make Qualified Health Plans (QHPs) available to eligible individuals and employers; and identifies the minimum functions an Exchange must perform. CMS and other federal partners will use the data collected from states operating SBEs to determine Exchange compliance with federal standards for operating the Exchange. The data that health insurance issuers, Exchanges, and other entities that Exchanges contract within performing Exchange functions collect will help to inform CMS, Exchanges, and health insurance issuers on the participation of individuals, employers, and employees in the individual Exchange and SHOP. *Form Number:* CMS-10593 (OMB control number: 0938-1312); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits and Not-for-profits institutions; *Number of Respondents:* 20; *Total Annual Responses:* 20; *Total Annual Hours:* 55,026. (For policy questions regarding this collection contact Tiffany Y. Animashaun at Tiffany.Animashaun@cms.hhs.gov).

Dated: December 5, 2023.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023-27035 Filed 12-7-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2022-E-2194, FDA-2022-E-2195, and FDA-2022-E-2196]

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

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 Tivdak 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 patents which claim 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 February 6, 2024. 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 June 5, 2024. 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 February 6, 2024. 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-2022-E-2194, FDA-2022-E-2195, and FDA-2022-E-2196 for “Determination of Regulatory Review Period for Purposes of Patent Extension; TIVDAK.” 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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

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 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 Tivdak (tisotumab vedotin). Tivdak is indicated for the treatment of adult patients with recurrent or metastatic cervical cancer

with disease progression on or after chemotherapy. Subsequent to this approval, the USPTO received patent term restoration applications for Tivdak (U.S. Patent Nos. 9,150,658; 9,168,314; and 9,492,565) from Genmab A/S, and the USPTO requested FDA’s assistance in determining the patents’ eligibility for patent term restoration. In a letter dated September 21, 2022, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of Tivdak 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 Tivdak is 2,959 days. Of this time, 2,736 days occurred during the testing phase of the regulatory review period, while 223 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 16, 2013. The applicant claims August 17, 2013, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 16, 2013, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

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):* February 10, 2021. FDA has verified the applicant’s claim that the biologics license application (BLA) for Tivdak (BLA B761208) was initially submitted on February 10, 2021.

3. *The date the application was approved:* September 20, 2021. FDA has verified the applicant’s claim that BLA B761208 was approved on September 20, 2021.

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 applications for patent extension, this applicant seeks 997 days, 1,077 days, or 1,190 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.

Dated: December 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26992 Filed 12–7–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2021–E–1091 and FDA–2022–E–0249]

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

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 Pemazyre 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 February 6, 2024. 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 June 5, 2024. 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 February 6, 2024. 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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- **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>.

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- 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–2021–E–1091 and FDA–2022–E–0249 for “Determination of Regulatory Review Period for Purposes of Patent Extension; PEMAZYRE.” 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>.

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FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration,