2. *Type of Information Collection Request:* Revision with change of the currently approved collection; *Title:* Medicare Part D Manufacturer Discount Program; *Use:* Congress enacted the Inflation Reduction Act of 2022, Public Law 117–169 (IRA). Section 11201 of the IRA eliminates the coverage gap phase of the Part D benefit. It also sunsets the coverage gap discount program (CGDP) after December 31, 2024, and amends the Social Security Act (the Act) to add section 1860D–14C, requiring the Secretary to establish a new Medicare Part D manufacturer discount program (MDP) beginning January 1, 2025. Under the MDP, participating manufacturers are required to provide discounts on their ''applicable drugs'' (brand drugs, biologics, and biosimilars) both in the initial coverage phase and in the catastrophic coverage phase of the Part D benefit.

Information in this collection is needed to set up agreements between manufacturers and CMS. Under section 1860D–14C(a) of the Act, such agreements are required for manufacturers in order to participate in the MDP and, under section 1860D43(a) of the Act, for their applicable drugs to be covered under Part D beginning in 2025. The information collected from manufacturers in the Health Plan Management System (HPMS) (Appendix A) is needed to create and execute MDP agreements and to determine which manufacturers qualify as a specified manufacturer or specified small manufacturer for phased-in discounts under section 1860D–14C(g)(4) of the Act. Banking information collected by the TPA from manufacturers and plan sponsors (Appendix B) is needed to prepare invoices and process financial transactions (deposits and payments) through the ACH. *Form Number:* CMS–10846 (OMB control number: 0938–1451); *Frequency:* Once; *Affected Public:* Private sector, Business or other for-profits and Not-for-profits institutions; *Number of Respondents:* 200; *Number of Responses:* 200; *Total Annual Hours:* 320. (For questions regarding this collection, contact Maricruz Bonfante at (410–786–5086).

3. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Emergency Preparedness Requirements for Medicare and Medicaid Providers Participating Providers and Suppliers; *Use:* This is a reinstatement of the information collection request that expired on January 31, 2023. The previous iteration of this OMB Control Number: 0938–1325 had a burden of 1,260,474 annual hours. For this requested reinstatement, with changes, the total annual burden hours for industry is 1,251,158 hours and the annual burden costs are $401,106,506.

Emergency Preparedness information collections were established as a result of the Omnibus final rule ''*Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers,*'' 81 FR 63860 (September 16, 2016) (hereinafter ''*2016 Final Rule*''). This information collection request captures the burden necessary for existing providers and suppliers to maintain their emergency preparedness collection of information requirements. This request also captures the burden to develop and implement the emergency preparedness requirements for newly approved Medicare and Medicaid providers and suppliers, also referred to as facilities.

This information collection (''IC'') is an ''Omnibus'' request. The emergency preparedness Conditions of Participation (CoPs) apply to the 19 Medicare and Medicaid providers that are listed in the next section. However, for reasons discussed below, this information collection request captures the burden for 17 of the affected Medicare and Medicaid providers and suppliers.

This is a departure, as we normally submit information collection requests (''ICRs'') by provider and supplier type. For example, the collection of information(s) stemming from the Conditions of Participation for the ''Hospital'' provider type are under OMB Control Number: 0938–0328. The collection of information(s) stemming from the Conditions of Participations for the ''Hospice'' provider type are under OMB Control Number: 0938–1067, etc. We make this exception for continuity and simplicity. We continue to cross reference this emergency preparedness IC in each provider type's individual information collection request.

In response to past terrorist attacks, natural disasters, and the subsequent national need to refine the nation's strategy to handle emergency situations, there continues to be a coordinated effort across Federal agencies to establish a foundation for development and expansion of emergency preparedness systems.

This reinstatement includes a new facility type, Rural Emergency Hospitals (REHs), which was created in 2021, after the prior reinstatement for this package had been approved in 2020. Congress introduced the designation Rural Emergency Hospitals (REHs) as part of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260), which is codified at 42 United States Code § 1395x(kkk)(1) or Section 1861(kkk)(1) of the Social Security Act. REHs are subject to the Emergency Preparedness CoPs per 42 CFR 485.542 and are similar to the Critical Access Hospital (CAH's) Emergency Preparedness CoPs. *Form Number:* CMS–10578 (OMB control number 0938–1325); *Frequency:* Annually; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profits institutions; *Number of Respondents:* 60,712; *Total Annual Responses:* 80,915; *Total Annual Hours:* 1,251,158. (For policy questions regarding this collection contact Claudia Molinar at 410–786–8445.)

William N. Parham, III,

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

[FR Doc. 2025–11324 Filed 6–18–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–0206; FDA–2024–E–0207; FDA–2024–E–0208]

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

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 QALSODY 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 August 19, 2025. 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 December 17, 2025. 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 August 19, 2025. 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 Numbers FDA–2024–E–0206; FDA–2024–E–0207; FDA–2024–E–0208 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; QALSODY.'' 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, 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, QALSODY (tofersen) indicated for the treatment of amyotrophic lateral sclerosis in adults who have a mutation in the superoxide dismutase 1 gene. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain observed in patients treated with QALSODY. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials. Subsequent to this approval, the USPTO received patent term restoration applications for QALSODY (U.S. Patent Nos. 10,385,341; 10,669,546; 10,968,453) from Biogen MA Inc. and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated February 6, 2024, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of QALSODY 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 QALSODY is 2,708 days. Of this time, 2,372 days occurred during the testing phase of the regulatory review period, while 336 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:* November 27, 2015. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 27, 2015.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* May 25, 2022. FDA has verified the applicant's claim that the new drug application (NDA) for QALSODY (NDA 215887) was initially submitted on May 25, 2022.

3. *The date the application was approved:* April 25, 2023. FDA has verified the applicant's claim that NDA 215887 was approved on April 25, 2023.

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 543 days, 697 days, or 755 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: June 13, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11315 Filed 6–18–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA–2025–N–1330]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Submissions of Medical Device Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with electronic submission of medical device registration and listing.

DATES: Either electronic or written comments on the collection of information must be submitted by August 19, 2025.

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 August 19, 2025. 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–N–1330 for ''Electronic Submission of Medical Device Registration and Listing.'' 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