

extended for a period of up to 5 years so long as the patented item (human drug 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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device SYMPLICITY SPYRAL RENAL DENERVATION SYSTEM. SYMPLICITY SPYRAL RENAL DENERVATION SYSTEM is indicated to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. Subsequent to this approval, the USPTO received patent term restoration applications for SYMPLICITY SPYRAL RENAL DENERVATION SYSTEM (U.S. Patent Nos. 8,131,371; 9,314,630; 9,314,644; and 9,452,017) from Medtronic Ireland Manufacturing Unlimited Company, and the USPTO requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated August 25, 2025, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of SYMPLICITY SPYRAL RENAL DENERVATION SYSTEM represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that the FDA determine the product's regulatory review period.

## II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for

SYMPLICITY SPYRAL RENAL DENERVATION SYSTEM is 3,161 days. Of this time, 2,801 days occurred during the testing phase of the regulatory review period, while 360 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective:* March 25, 2015. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective March 25, 2015.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e):* November 23, 2022. The applicant claims November 8, 2022, as the date the premarket approval application (PMA) for SYMPLICITY SPYRAL RENAL DENERVATION SYSTEM (PMA P220026) was initially submitted. However, FDA records indicate that PMA P220026 was submitted on November 23, 2022.

3. *The date the application was approved:* November 17, 2023. FDA has verified the applicant's claim that PMA P220026 was approved on November 17, 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 application for patent extension, this applicant seeks 1,491, 1,571 or 1,767 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.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2025–N–6869]

### Agency Information Collection Activities; Proposed Collection; Comment Request; Medication Guides for Prescription Drug Products

**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 Medication Guides for prescription drug products.

**DATES:** Either electronic or written comments on the collection of information must be submitted by March 30, 2026.

**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 No. FDA-2025-N-6869 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Medication Guides for Prescription Drug Products." 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 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:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "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 (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Medication Guide Requirements for Prescription Drug Product Labeling

OMB Control Number 0910-0393—Extension

This information collection supports FDA regulations pertaining to the distribution of patient labeling, called Medication Guides, for human prescription drug and biological products used primarily on an outpatient basis, and required for products that pose a serious and significant public health concern. The regulations are codified in part 208 (21 CFR part 208): *Medication Guides for Prescription Drug Products* and set forth general requirements including both content and format, as well as provide for exemptions and deferrals. Medication Guides provide patients with important information about drug products, including the drug's approved uses, contraindications, adverse drug reactions, and cautions for specific populations, and are required in accordance with Agency regulations.

To assist both consumers and industry with understanding the applicable regulatory requirements and purpose of Medication Guides, we have developed resources and made them available on our website at <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-labeling-resources#medication-guides>. Among the resources, we include the guidance document entitled *Medication Guides—Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS)* (November 2011) (available at <https://www.fda.gov/media/79776/download>), as well as a discussion of the distinction between Medication Guides and Consumer Medication Information. The regulations, guidance, and informational resources are

intended to improve the public health by enabling patients to use certain medications most safely and effectively.

As part of the new drug application process (21 CFR part 314), we review Medication Guides to determine whether the labeling for certain

prescription drug products and biological products comply with the applicable regulations.

*Description of Respondents:* Respondents to this collection of information are holders and sponsors of applications, distributors of prescription

drug products, and authorized dispensers of prescription drug products (pharmacists).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Content and format of a Medication Guide; § 208.20 .....	70	1	70	320	22,400
Exemptions and deferrals; § 208.26(a) .....	1	1	1	4	4
<b>Total</b> .....			<b>71</b>		<b>22,404</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on our evaluation of data from our records, we estimate that, in the next three years, 70 holders of applications will prepare and submit one Medication Guide annually for our review. We estimate that the application holders will spend approximately 320 hours to prepare and submit the Medication Guide. In addition, we

estimate that, in the next three years, one sponsor of one of the new or supplementary applications will request an exemption under § 208.26(a) from at least some of the Medication Guide format or content requirements, annually. We estimate that the sponsor will spend approximately 4 hours to prepare and submit the request for

exemption. Our estimated burden for the information collection reflects an overall increase of 9,280 hours and a corresponding increase of 29 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure <sup>2</sup>	Total hours
Distributor provides Medication Guides to authorized dispensers; § 208.24(c).	191	9,000	1,719,000	1.25 .....	2,148,750
Authorized dispenser provides Medication Guides to patients; § 208.24(e).	88,736	5,705	506,238,880	0.05 (3 minutes).	25,311,944
<b>Total</b> .....			<b>507,957,880</b>		<b>27,460,694</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Numbers may not sum due to rounding.

We estimate that, in the next three years, 191 distributors will provide Medication Guides to approximately 9,000 authorized dispensers, annually. We estimate that the dispensers will spend approximately 1.25 hours to prepare and distribute the Medication Guides. Under 21 CFR 201.24(e), authorized dispensers are required to provide a Medication Guide directly to the patient (or the patient’s agent) upon dispensing a product for which a Medication Guide is required. We estimate that, in the next three years, 88,736 authorized dispensers will provide Medication Guides to approximately 5,705 patients, annually. We estimate that authorized dispensers will spend approximately 3 minutes to provide the Medication Guide to a patient.

We have increased our estimated burden associated with disclosures to

reflect an increase in related submissions over the past 3 years.

**Brian Fahey,**  
Associate Commissioner for Legislation.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2024–E–2147]

**Determination of Regulatory Review Period for Purposes of Patent Extension; RYZNEUTA**

**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 RYZNEUTA 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 March 30, 2026. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence