4164-01-P

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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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, PRAStaff@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[1]

Activity; 21 CFR Section	No. of Respondents	No. 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
Total			71		22,404

[1] 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[1]

Activity; 21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure[2]	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
Total			507,957,880		27,460,694

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 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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