4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0902]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medication Guides for Prescription Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0393. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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. Applicable regulations are codified at part 208 (21 CFR part 208): Medication Guides for Prescription Drug Products, and set forth general content and format requirements, as well as provide for exemptions and deferrals. Medication Guides provide patients with important written 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 consumers and industry with understanding applicable regulatory requirements in part 208 pertaining to developing, distributing, and submitting certain Medication Guides, we have developed the guidance document entitled "Medication Guides--Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS)" (available at https://www.fda.gov/media/79776/download). The guidance document includes: (1) a discussion of the applicable regulations; (2) FDA enforcement policy with regard to Medication Guides associated with products dispensed to healthcare professionals, or patient caregivers, instead of being dispensed directly to the patient for self-administration; and (3) Medication Guides required as part of a risk evaluation and mitigation strategy.

In the *Federal Register* of March 22, 2022 (87 FR 16199), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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	41	1	41	320	13,120
Exemptions and deferrals; § 208.26(a)	1	1	1	4	4

Total			42		13,124

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

Upon evaluation of the information collection, we have removed burden we attributed to reporting associated with supplements and other changes to approved abbreviated new drug applications, new drug applications, and biologics license applications (21 CFR 314.70(b)(3)(ii) and 601.12(f)). We now account for burden associated with these regulatory provisions in OMB control numbers 0910-0001 and 0910-0338 and have decreased the burden associated with this collection accordingly.

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
Distribute Medication Guides to authorized dispensers; § 208.24(c)	191	9,000	1,719,000	1.25	2,148,750
Distribute and Dispense Medication Guides to Patients; § 208.24(e)	88,000	5,705	502,040,000	0.05 (3 minutes)	25,102,000
Total			503,759,000		27,250,750

[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 have decreased our estimated burden associated with disclosures to reflect a decrease in related submissions over the past 3 years.

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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