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; Prescription Drug Product Labeling; Medication Guide Requirements

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 (PRA).

DATES: Fax written comments 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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 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.

Prescription Drug Product Labeling; Medication Guide Requirements

OMB Control Number 0910-0393--Extension

FDA regulations require the distribution of patient labeling, called Medication Guides, for certain prescription human drug and biological products used primarily on an outpatient basis that pose a serious and significant public health concern. Medication Guides provide patients the most important information about drug products, including the drugs' approved uses, contraindications, adverse drug reactions, and cautions for specific populations. These regulations are intended to improve the public health by providing information necessary for patients to use certain medications safely and effectively.

The regulations contain the following reporting requirements that are subject to the PRA:

- § 208.20 (21 CFR 208.20)--Applicants must submit draft Medication Guides for FDA approval according to the prescribed content and format.
- §§ 314.70(b)(3)(ii) and 601.12(f) (21 CFR 314.70(b)(3)(ii) and 21 CFR 601.12(f))--Application holders must submit changes to Medication Guides as supplements to their applications to FDA for approval.
- § 208.24(c) (21 CFR 208.24(c))--Each distributor or packer who receives Medication Guides, or the means to produce Medication Guides, from a manufacturer under paragraph (b) of this section shall provide those Medication Guides to each authorized dispenser to whom it ships a drug product.
- § 208.24 (e) (21 CFR 208.24(e))--Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide a Medication Guide

directly to each patient when dispensing the product to the patient or to the patient's agent, unless an exemption applies under § 208.26 (21 CFR 208.26).

- § 208.26(a)--Requests may be submitted for an exemption or a deferral from particular Medication Guide content or format requirements.

In the *Federal Register* of October 26, 2018 (83 FR 54110), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received encouraging the use of "provider-neutral language" in places where terms such as "doctor" or "physician" are used suggesting that these terms may cause some confusion for patients. We are appreciative of this recommendation; however, we decline to implement such changes.

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

Table 1.--Estimated Annual Reporting Burden[1]

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	61	1	61	320	19,520
Supplements and Other Changes to an Approved Application--§§ 314.70(b)(3)(ii) and 601.12(f)	155	1	155	72	11,160
Exemptions and Deferrals--§ 208.26(a)	1	1	1	4	4
Total					30,684

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

Table 2.--Estimated Annual Third-Party Disclosure Burden[1]

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Distributing Medication Guide to Authorized Dispenser--§ 208.24(c)	191	9,000	1,719,000	1.25	2,148,750
Distributing and Dispensing a Medication Guide	88,736	5,705	506,238,880	0.05 (3 minutes)	25,311,944

to Patient--§ 208.24(e)					
Total					27,460,694

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

Our estimated annual reporting burden for the information collection reflects an overall increase of 4,664 total hours. We attribute this adjustment to an increase in the number of submissions we received over the last few years. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our annual third-party disclosure burden estimate.

Dated: August 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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