UNITED STATES FOOD & DRUG ADMINISTRATION

Medication Guides for Prescription Drug Products:
21 CFR Part 208

OMB Control No. 0910-0393 - Extension

Summary of Changes: *As a result of public comment, together with a reexamination of previous submissions for OMB review and approval, we have significantly revised our assessment of the disclosure burden resulting in an increase in responses and a decrease in hours,. We discuss this fully in our 30-day notice and in Q-15 below. No forms are associated with the ICR.*

SUPPORTING STATEMENT – **Part A: Justification:**

1. Circumstances Making the Collection of Information Necessary

This information collection supports the Food and Drug Administration (FDA, the agency, or we) regulations pertaining to 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. The regulations are codified in 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 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 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), 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.

We are requesting a reinstatement of OMB approval for the information collection, noting changes and adjustments below.

2. Purpose and Use of the Information Collection

Included among the requirements in 21 CFR part 314 that govern applications for FDA approval to market a new drug is the submission of any Medication Guide (see 21 CFR part 314.50), as applicable under 21 CFR part 208, as well as any supplemental changes (see 21 CFR 314.70). The Agency uses the information submitted to determine whether the Medication Guide complies with applicable regulatory requirements. Information collection activities applicable to

regulations in 21 CFR part 314 are currently approved in OMB control no. 0910-0001. In this request FDA is accounting for information collection burden we believe attributable to regulatory requirements in 21 CFR part 208.

3. Use of Improved Information Technology and Burden Reduction

Labeling under part 208 may be submitted in electronic format provided it is submitted in a form that FDA can process, review, and archive. Because the labeling is submitted as part of the application process for new drug applications (NDA), biologics license applications (BLA), and abbreviated new drug applications (ANDA), we believe this helps minimize burden on respondents. FDA provides resources to industry, including guidance, regarding the submission of information in electronic format.

4. Efforts To Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Although other ICRs cover specific labeling requirements (OMB control numbers 0910-0001, 0910-0338, and 0910-0572), this ICR specifically relates to the collection of information associated with human prescription drugs, including biological products, subject to part 208.

5. Impact on Small Businesses or Other Small Entities

We believe the information collection imposes no undue burden on small entities.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements associated with the labeling of human prescription drugs, including biological products.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the *Federal Register* Notice and Efforts to Consult Outside the Agency

In the *Federal Register* of January 27, 2026 (91 FR 3511), we published a 60-day notice requesting public comment on the proposed collection of information. We received a number of comments. Some comments discussed FDA's proposed rule (RIN 0910-AH68) that issued on May 31, 2023, "Medication Guides: Patient Medication Information (PMI)," (88 FR 35694). While we reviewed these comments in the context of this reinstatement request, we have also added them to the rulemaking docket (FDA-2019-N-5959) for continued consideration. Other comments communicated general support for improving the content, clarity, and readability of Medication Guides, including the use of electronic delivery. Finally, some comments questioned the accuracy of FDA's burden assessment attributable to authorized dispensers who provide Medication Guides to patients. FDA is most appreciative of all public input regarding its information collection activities and as a result of these latter comments, together with a reexamination of previous submissions for OMB review and approval of ICR 0910-0393, we have significantly revised our assessment of the disclosure burden attributable to requirements established in 21 CFR part 208 for distributors and

authorized dispensers of Medication Guides.

Our 60-day notice states that respondents to the information collection are sponsors of new drug applications, distributors of prescription drug products, and authorized dispensers of prescription drug products. We determined the number of respondents to the annual recordkeeping requirements based on the number of new drug sponsors whose product applications we believe are subject to the requirements in 21 CFR 208, consistent with internal Agency data and a recent preliminary regulatory impact analysis in support of rulemaking RIN 0910-AH68. We retain those estimates provided in our 60-day notice, as reflected below in table 1.

9. Explanation of Any Payment or Gift to Respondents

No remuneration is provided to respondents to the information collection.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. This ICR does not collect personally identifiable information (PII) or information of a personal nature. Information collected is about unapproved new drugs and biological products and is collected to comply with regulations. Respondents submit information regarding the design and testing of new drug applications (NDA) and biologics license applications (BLA). Because neither FDA nor any party acting on behalf of the agency collects PII, the ICR is not subject to the Privacy Act of 1974 and the requirements of the Privacy Act such as displaying a Privacy Act Statement on a collection form do not apply.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

This reporting burden does not involve any sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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

Activity; 21 CFR Section 208 (Obtaining the PMI)	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.

Included among the requirements in 21 CFR part 314 that govern applications for FDA approval to market a new drug is the submission of any Medication Guide (see 21 CFR part 314.50), as applicable under 21 CFR part 208, as well as any supplemental changes (see 21 CFR 314.70). We use the information submitted to determine whether the Medication Guide complies with applicable regulatory requirements. Information collection activities applicable to regulations in 21 CFR part 314 are currently approved in OMB control no. 0910-0001. In this request FDA is accounting for information collection burden we believe attributable to regulatory requirements 21 CFR part 208.

Noting that 5 CFR 1320.3(m) defines a recordkeeping requirement to include the reporting to the Federal government regarding such records, we have characterized the submission of Medication Guides to FDA as reporting activity required as a function of certain NDA submissions. Based on our evaluation of internal data, 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 expend 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 assume sponsors will expend an average of 4 hours annually to prepare and submit a request for exemption.

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

Activity; 21 CFR Section 208 (Providing the PMI for Distribution)	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure[2]	Total Hours
Manufacturer ensures that Medication Guides are provided in adequate supply to authorized dispensers, or provides means to produce Medication Guide; § 208.24(b)(1) and (b)(2)	70	9,000	630,000	1.25	787,500
Distributor provides Medication Guides or means to produce to authorized dispensers § 208.24(c)	191	9,000	1,719,000	1.25	2,148,750
Dispensing Medication Guide to patient 208.24(e)	88,736	5,705	506,238,880	.0027	1,366,845
Total			508587880		4303095

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Figures have been rounded to the nearest one, one-thousandth..

Assuming that the same 70 application holders of products requiring Medication Guides must ensure that distributors and authorized dispensers are provided with an adequate supply or means to produce the required Medication Guide, as required under 21 CFR 208.24(b)(1) and (b)(2), we calculate an average of 9,000 disclosures annually and an average of 1.25 hours per disclosure, as reflected in row 1, table2.

Similarly, assuming 12% of 1,600 distributors (191), based on figures consistent with, accounted for, and approved in OMB control number 0910-0806 (Pharmaceutical Distribution Supply Chain) will ship drug products that require a Medication Guide and must provide the Medication Guide or the means to produce it to authorized dispensers, as required under 21 CFR 208.24(c), we calculate an average of 9,000 disclosures annually and an average of 1.25 hours per disclosure, as reflected in row 2, table 2.

Regarding authorized dispensers, we currently assume 88,736 authorized dispensers based on informal data and reports from various pharmacy trade associations and have retained this figure. We also retain our estimated average of 5,705 patients to whom Medication Guides will be distributed annually. However, we have revised the time we attribute necessary to the task of dispensing Medication Guides to patients, as required under 21 CFR part 208.24(e). FDA originally proffered 5 seconds in its proposed rule of August 24, 1995 (60 FR 44182) inviting comment under the Paperwork Reduction Act of 1980. In our final rule on December 1, 1998 (63 FR 66378), after enactment of the Paperwork Reduction Act of 1995, FDA again estimated 5 seconds of burden for the task of dispensing a Medication Guide to a patient and invited public comment. No comments were posted to the rulemaking docket (Legacy Docket No. 93-0371; RIN 0910-AA37) regarding the 5-second estimate.

12b. Annualized Cost Burden Estimate

While we estimate an average of 70 Medication Guides are submitted annually by product sponsors, we account for this cost under OMB control no. 0910-0001. We assume distributor costs to be usual and customary. At the same time, we estimate a median hourly wage rate of $66.10 using BLS 2026 data and calculate the average cost to dispensers to be $284,434,579.50 annually (4,303,095 x $66.10).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, or operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Because review of prescription drug product labeling is part of FDA's review of an underlying application submission (as required under 21 CFR parts 314 and 601, and approved in control nos. 0910-0001 and 0910-0338), we expect most costs for the information collection have been accounted for in the respective ICRs. However, to reflect costs for determinations made under 21 CFR 208, we factor current Prescription Drug User Fee rates and annual respondent burden hours to calculate an estimated $1,001,407.27 to the Federal Government annually.

15. Explanation for Program Changes or Adjustments

The ICR includes changes and adjustments, as follows:

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses	508,587,951	0	0	4,829,782	503,758,169	0
Annual Time Burden (Hr)	4,325,499	0	0	-22,938,375	27,263,874	0
Annual Cost Burden ($)	0	0	0	0	0	0

IC Title	Status	Responses	Hours	Modification/Change
Content and Format of Medication Guide	Modified	70	22400	**No. of respondents updated based on current agency data.**
Exemptions and Deferrals	Unchanged	1	4	**None.**

Distributor provides Medication Guide or means to produce to Dispenser	Modified	1719000	2148750	**Modified title only, to distinguish tasks applicable to other respondent group with independent regulatory requirement under 21 CFR 208.24(c).**
Dispensing Medication Guide to patient	Modified	506238880	1366845	**Modified time per response to reflect adjusted agency estimate, and to reflect independent requirement applicable under 21 CFR 208.24(e); significant decrease to annual hours.**
Mfr. provides PMG or means to produce to distributers & authorized dispensers	New	630000	787500	**Added IC element to account for burden applicable to discrete respondent group under 208.24(a); increases annual responses.**
TOTAL		508587951	4325499	

Previously, FDA calculated burden we believe attributable to requirements in 21 CFR 208.24 and applied our assessment to manufacturers, distributors, and authorized dispensers collectively. Upon reexamination of the information collection requirements applicable to 21 CFR part 208.24, we have separated burden to align with tasks that apply to manufacturers, distributors, and authorized dispensers, respectively, as reflected in table 2 at Question 12 of this supporting statement, and in our 30-day publication of July 1, 2026.

Specifically, FDA originally proffered 5 seconds in its proposed rule of August 24, 1995 (60 FR 44182) for the task of dispensing the Medication Guides to patients, inviting comment under the Paperwork Reduction Act of 1980. In our final rule on December 1, 1998 (63 FR 66378), after enactment of the Paperwork Reduction Act of 1995, FDA again estimated 5 seconds of burden for the task of dispensing a Medication Guide to a patient and invited public comment. No comments were posted to the rulemaking docket (Legacy Docket No. 93-0371; RIN 0910-AA37) regarding the 5-second estimate.

Upon further review, we find that in 2008 we revised our original estimate for dispensing the medication guide from 5 seconds to 3 minutes based on a public comment that the estimate had remained unchanged since 1998, "while the **program** continue[d] to expand in an unchecked manner," (emphasis added), and that FDA's estimate failed to consider "**realities** pharmacists face in complying with the program" (emphasis added). See Docket No. FDA-2008-N-0162. We have now adjusted that estimate to 10 seconds and believe this is consistent with current submission figures and the specific tasks required in 21 CFR part 208, noting the following:

- As required by the PRA of 1995, FDA has confined its estimate of burden attributable to that we believe is required by 21 CFR 208.24(e), which entails the task of dispensing the Medication Guide. Effort that may be attributable to counseling patients, dispensing literature not required by 21 CFR 208.24(e), and to patients reading the Medication Guide is not included in our estimate.
- As provided for by the PRA of 1995, FDA believes that tasks that may be associated with dispensing a Medication Guide, such as counseling patients, dispensing literature

not required by our regulations, and recordkeeping that may be required by other authorities such as State licensing agents and the Drug Enforcement Administration, to be usual and customary as part of the practice of pharmacy. Therefore, we estimate no burden for efforts relating to tasks that fall beyond the scope of 21 CFR part 208.

- Consistent with the PRA, FDA does account for various tasks that may be performed by authorized dispensers in its active collection inventory including OMB control numbers 0910-0800 (Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act); 0910-0806 (Pharmaceutical Distribution Supply Chain); and 0910-0858 (Human Drug Compounding, Repackaging, and Related Activities Regarding Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act).

16. Plans for Tabulation and Publication and Project Time Schedule

    FDA does not intend to publish tabulated results of the information collection.

17. Reason(s) Display of OMB Expiration Date Is Inappropriate

    The OMB expiration date will be displayed as required by 5 CFR 1320.8(b)(1).

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.