UNITED STATES FOOD & DRUG ADMINISTRATION

Prescription Drug Product Labeling
Medication Guide Requirements

OMB Control No. 0910-0393

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency, us 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 at 21 CFR part 208 (21 CFR 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 www.fda.gov. Among the resources we include the guidance document entitled, "*Medication Guides — Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS)*"; 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.

Accordingly, we are requesting extension of OMB approval for the information collection provisions under 21 CFR 208 and discussed in the supporting statement.

2. Purpose and Use of the Information Collection

As part of the new drug application process (21 CFR 314), FDA reviews Medication Guides to determine whether the labeling for certain prescription drug products and biological products comply with the applicable regulations. In turn, the information will then inform patients to whom these products are administered thereby promoting the safe and effective use of human prescription drug and biological products.

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 NDAs, BLAs, and ANDAs, we believe this helps minimize burden on respondents. FDA provides resources to industry, including guidance, regarding the submission of information in electronic format. These resources are available on our website at https://www.fda.gov/Drugs/ResourcesForYou/Industry/default.htm.

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

No undue burden is imposed on small entities as a result of the information collection. At the same time, we provide assistance to sponsors of NDAs, BLAs, ANDAs, and authorized packers and dispensers of human prescription drugs, including biological products through industry guidance available at https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/guidances/ucm065016.htm and through the Center for Drug Evaluation and Research's (CDER) Office of Small Business and Industry Assistance.

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 accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the Federal Register of October 26, 2018, 2018 (83 FR 54110). We received one comment suggesting that the use of "*provider-neutral language*" be incorporated into the Medication Guide regulations. While we are appreciative of this comment, we decline to adopt the suggestion at this time.

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

We have reviewed this information collection to identify any potential risks to the privacy of individuals whose information may be handled by or on behalf of FDA and to ensure appropriate handling of information that may require privacy protection under the Privacy Act. In this case, this information collection does not involve solicitation or collection of personally identifiable information (PII) by or on behalf of FDA/CDER. Specifically, FDA/CDER does not intend to collect personally identifiable information (PII) and will not maintain records subject to the Privacy Act or otherwise operate a Privacy Act System of Records in relation to this specific collection.

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

We estimate the burden for the information collection as follows:

Table 1.--Estimated Annual Reporting Burden

IC Activity; 21 CFR citation	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Content and format of a Medication Guide; § 208.20	61	1	61	320	19,520
Supplements/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			217		30,684

Table 2.--Estimated Annual Third-Party Disclosure Burden

IC Activity; 21 CFR citation	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure	Total Hours
Distribution: MGs to authorized dispenser; § 208.24(c)	191	9,000	1,719,000	1.25	2,148,750
Distributing and Dispensing a Medication Guide to Patient-- § 208.24(e)	88,736	5,705	506,238,880	0.05 (3 mins.)	25,311,944
TOTAL			507,957,880		27,460,694

12b. Annualized Cost Burden Estimate

We estimate an average of 61 Medication Guides are submitted annually. Assuming each Medication Guide requires 320 hours to prepare and submit to FDA, the industry cost, based on and hourly rate of $75 per hour, is estimated at $1,464,000 (19,520 hours x $75/hr). We estimate the cost of developing each Medication Guide to supplement existing applications would is $6,100, and the cost for each generic drug Medication Guide is approximately $610.

FDA estimates that the 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. FDA estimates that this will entail approximately 4 hours of work, or approximately $300 (4 x $75/hr).

In addition, FDA estimates that 155 existing Medication Guides annually might require minor change under § 314.70 (b)(3)(ii) or § 601.12 (f), necessitating 11,160 hours of full-time effort or $837,000 (11,160 hours x $75/hr).

Under § 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. This distribution of a Medication Guide to a patient is estimated to require 3 minutes of a pharmacist's time, $1,673,626,000 (25,311,944 hours x $66.12/hr) annually.

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

Costs to the Federal government are absorbed through existing resource allocations covering the review of NDAs, BLAs, and ANDAs.

15. Explanation for Program Changes or Adjustments

The information collection reflects an upward adjustment in the number of respondents, which we attribute to an increase in submissions we have received over the past few years. We have also corrected a calculation error in our annual third-party disclosure burden. These adjustments result in an overall increase of 51 annual responses and 4,708 annual hours.

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 1320.8(b)(1).

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.