Prescription Drug Product Labeling Medication Guide Requirements

OMB Control No. 0910-0393

SUPPORTING STATEMENT

Justification

1. Circumstances Making the Collection of Information Necessary

Food and Drug Administration (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. These Medication Guides inform patients about the most important information they should know about these products in order to use them safely and effectively. Included in the Medication Guide (MG) is information such as the drug's approved uses, contraindications, adverse drug reactions, and cautions for specific populations, with a focus on why the particular product requires a Medication Guide. The regulations are intended to improve the public health by providing information necessary for patients to use certain medication safely and effectively.

While sponsors of New Drug Applications (NDAs), Biologics License Applications (BLAs), and Abbreviated New Drug Applications (ANDAs) are subject to general labeling requirements under regulations found in 21 CFR Parts 314 and 601, this information collection specifically addresses patient labeling for human prescription drug products, including biological products, as set forth under 21 CFR part 208.

21 CFR 208.20 explains the content and format of a Medication Guide that must be submitted for FDA approval. Under regulations found at 21 CFR part 314.50 and 21 CFR 601.2, applicants are required to provide this information to FDA as part of the subject application. Similarly, when supplements or changes are necessary to current drug and biologics applications, under 21 CFR 314.70(b) (3) (ii) and 21 CFR 601.12(f), applicants are required to submit any changes to the Medication Guide for FDA approval.

21 CFR 208.24(c) requires a distributor or packer that receives Medication Guides, or the means to produce Medication Guides, to provide those Medication Guides to each authorized dispenser to whom it ships a container of the drug product.

21 CFR 208.24(e) requires that each authorized dispenser of a prescription drug product for which a Medication Guide is required, when dispensing the product to a patient or to a patient's agent, provide a Medication Guide directly to each patient unless exempt under 21 CFR 208.26.

21 CFR 208.26(a) allows applicants to submit requests for exemption or deferral from particular Medication Guide content or format requirements.

FDA is therefore requesting OMB approval for the information collection associated with these regulations.

2. Purpose and Use of the Information Collection

This information collection enables the agency to determine whether the labeling for certain prescription drug products and biological products complies with 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 21 CFR part 208 may be submitted in electronic format provided that 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 to minimize burden on respondents. FDA provides resources to industry, including guidance, regarding the submission of information in electronic format. These resources are available on the agency's website at http://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. While other information collection requests cover specific labeling requirements (OMB Control Nos. 0910-0001, 0910-0338, and 0910-0572), this information collection specifically relates to the collection of information associated with human prescription drugs, including biological products, subject to 21 CFR part 208.

5. Impact on Small Businesses or Other Small Entities

The information collection applies to all sponsors of NDAs, BLAs, ANDAs, and authorized packers and dispensers of human prescription drugs, including biological products. FDA offers assistance to small businesses through industry guidance available at http://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 (SBIA).

6. Consequences of Collecting the Information Less Frequently

Frequency of reporting is consistent with the statutory requirements associated with the labeling of human prescription drugs, including biological products.

7. Special Circumstances Relating to the Guidelines in 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), FDA published a 60-day notice in the Federal Register of May 29, 2015 (80 FR 30688). FDA received one comment in response to the notice requesting clarification of FDA's burden estimates for 21 CFR 208.24(c) (burden incurred by distributers of Patient Medication Guides). The agency addressed the comment in its 30-day notice that published on November 3, 2015 (80 FR 67762) attempting to provide such clarification, however the agency will be particularly mindful of estimating burden for this disclosure burden as FDA undertakes rulemaking to revise its patient medication information labeling regulations (0910-AH33).

9. Explanation of Any Payment or Gift to Respondents

There is no payment to respondents

10. Assurance of Confidentiality Provided to Respondents

This reporting burden has no confidentiality implications.

11. Justification for Sensitive Questions

This reporting burden does not involve any sensitive question.

12. Estimates of Annualized Burden Hour and Costs

12a. Annualized Hour Burden Estimate

We estimate the burden associated with the information as follows:

Table 1--Estimated Annual Reporting Burden

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
208.20; MGs submitted w/NDAs and BLAs	57	1	57	320	18,240
208.20; MGs submitted as supplements or updates	108	1	108	72	7,776
208.26(a); Exemptions and deferrals	1	1	1	4	4
TOTAL					26,020

[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	Avg. Burden per Disclosure	Total Hours
208.24(c); MG from packer/distributor to authorized dispenser	191	9,000	1,719,000	1.25	2,148,750
208.24(e); MG from authorized dispenser to patient	88,736	5,705	506,238,000	0.05 (3 mins.)	25,311,900
TOTAL			507,957,000		27,460,650

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

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

Compliance with requirements for Medication Guides is reviewed on a product-by-product basis contemporaneously with the review of NDAs, BLAs, and ANDAs. We therefore estimate no cost to the Federal government for this collection as expenditure for this review is calculated under collections 0910-0001 (NDAs) and 0910-0338 (BLAs).

15. Explanation for Program Changes or Adjustments

FDA has adjusted its estimates associated with the collection as follows:

IC	Responses	Hours
1 – MGs submitted as part of NDAs and BLAs	+32	+10,240
2 – MGs submitted as updates	+103	+7,416
3 – Exemptions and deferrals	0	0
4 – MGs from packers/distributers to authorized dispensers	0	0
5 – MGs from authorized dispensers to patients	+211,238,000	+10,561,900
TOTAL	211,238,135	10,579,556

We note that the increase to IC 5 (Medication Guides from authorized dispensers to patients under 21 CFR 204.24(e)) reflects adjustments over a six year period during which nearly 150 pharmaceuticals requiring the issuance of Patient Medication Guides have been included. Additionally, we have revised the number of respondents to reflect information reported by the National Association of Boards of Pharmacy (NABP) in a 2013 Survey of Pharmacy Law. Although there are no estimates for the average number of medications distributed annually at a single pharmacy, we can estimate the numbers associated with 208.24(e) based on a percentage of products that have a medication guide. Of an estimated 3500 Reference Listed Drug (RLD) products, 425, or 12.14%, have medication guides. Thus, multiplying the total number of

prescriptions filled annually (4.17 billion) by the percentage of those with medication guides (12.14 %) reflects 506,238,000 annual disclosures. Dividing the number of total annual disclosures (506,238,000) by the number of pharmacies (88,736), shows 5,705 disclosures per respondent. And finally, multiplying the total annual disclosures (506,238,000) by the average burden per disclosure, reflects a total of 25,311,900 burden hours annually for this IC.

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

While there are no forms associated with this collection of information, the agency will display OMB expiration as appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.