UNITED STATES FOOD & DRUG ADMINISTRATION

Requirements on Content and Format of Labeling
for Human Prescription Drug and Biological Products

OMB Control No. 0910-0572

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

Food and Drug Administration (FDA, us or we) regulations governing drugs set forth specific requirements regarding the content and format of labeling for human prescription drug and biological products. The regulations also provide for a waiver from the labeling requirements. The regulations are codified at 21 CFR part 201. Specifically, part 201.56 requires that prescription drug labeling contain certain information in the format specified in either § 201.57 (21 CFR 201.57) or § 201.80 (21 CFR 201.80), depending on when the drug was approved for marketing. Section 201.56(a) sets forth general labeling requirements applicable to all prescription drugs. Section 201.56(b) specifies the categories of new and more recently approved prescription drugs subject to the content and format requirements in §§ 201.56(d) and 201.57. Section 201.56(c) sets forth the schedule for implementing these revised content and format requirements. Section 201.56(e) specifies the sections and subsections, required and optional, for the labeling of older prescription drugs not subject to the revised format and content requirements. Section 201.58 sets forth procedures for requesting that FDA waive any requirement under §§201.56, 201.57, and 201.80. Older drugs not subject to the revised labeling content and format requirements in § 201.57 are subject to labeling requirements at § 201.80. Section 201.80(f)(2) requires that, within 1 year, any FDA-approved patient labeling be referenced in the "*Precautions*" section of the labeling of older products and either accompany or be reprinted immediately following the labeling.

We therefore request extension of OMB approval for the information collection provisions found in 21 CFR parts 201 as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The labeling regulations discussed in this supporting statement are part of FDA's strategic initiative to manage the risks of medical product use and reduce adverse events involving the products that it regulates. We intend the regulations on the content and format of labeling to make it easier for health care practitioners to access, read, and use information in prescription drug labeling, thereby increasing the extent to which they rely on labeling to obtain information. We believe compliance with the regulations will enhance the safe and effective use of prescription drug products, and in turn, reduce the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information. The requirements are important to the success of other initiatives aimed at improving patient care and decreasing the likelihood of medication errors. For example, the DailyMed, a collaboration

between FDA and the National Library of Medicine will be an innovative means of disseminating up-to-date and comprehensive medication information electronically for use in information systems that support patient care. The DailyMed will make current information about FDA-regulated products readily available to physicians, other health care practitioners, and patients. In addition, prescription drug labeling in the new format may also be utilized with electronic prescribing systems under development.

3. Use of Improved Information Technology and Burden Reduction

Drug product labeling covered by the regulations are submitted to FDA for approval as part of a new drug application (NDA), an abbreviated new drug application (ANDA), a biologics license application (BLA), or a supplement to an application. These applications and associated submissions are reported electronically. We have issued a number of guidance documents to assist respondents with the information collection, including recommendations for specific products. All guidance documents are available from our website at: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/default.htm

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection, although we have established other ICRs that cover specific labeling requirements and/or agency guidance (see, e.g., OMB Control Nos. 0910-0340 (OTC labeling), 0910-0624 (labeling for pregnant/lactating patients), and 0910-0670 (hypertension indications)).

5. Impact on Small Businesses or Other Small Entities

The information collection does not impose undue burden on small entities. Respondents to the collection provide labeling information to FDA as part of the drug and biological product application review process. We provide assistance to small businesses through agency guidance available on our website, as well as through our small business assistance staff in our Center for Drug Evaluation and Research (CDER).

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with the 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 inviting public comment in

the Federal Register of July 20, 2018 (83 FR 34596). We received two comments. One comment encouraged the use of "*provider-neutral language*" in specific regulations. The second comment discussed the distribution of package inserts for prescription drugs via paper labeling. Because these comments do not apply to the regulations associated with the information collection, they were not addressed.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of the information submitted under these regulations is protected under 21 CFR 314.430, 21 CFR 601, and 21 CFR part 20. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)).

11. Justification for Sensitive Questions

There are no questions of a sensitive nature included in the information collection.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

We estimate the burden of the information collection as follows:

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

21 CFR Part and Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Labeling Requirements in §§ 201.56 and 201.57	406	1.332	541	2,327	1,258,907

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

12b. Annualized Cost Burden Estimate

Assuming an average pharmaceutical industry wage rate of $75.00 per hour for preparing and submitting the required information, and multiplying that figure by the total burden hours, we estimate a cost to respondents of $94,418,025.

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 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 resource allocations are accounted for under collections 0910-0001 (NDAs) and 0910-0338 (BLAs).

15. Explanation for Program Changes or Adjustments

The information collection reflects an overall increase of 599,154 hours and a corresponding increase of 344 annual responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

16. Plans for Tabulation and Publication and Project Time Schedule

We do 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 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.