

UNITED STATES FOOD & DRUG ADMINISTRATION

Labeling Requirements for Prescription Drugs

OMB Control Number 0910-0572

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency) regulations governing the labeling of prescription drugs. The regulations are codified in 21 CFR part 201, subpart B (21 CFR 201.50 through 201.58) and set forth both general requirements, as well as specific content and format requirements. The regulations also provide for requesting a waiver from any labeling requirement and do not apply to biological products that are subject to the requirements of section 351 of the Public Health Service Act.

We are revising the information collection to include burden associated with regulations applicable to medical gas labeling found in § 201.328 (21 CFR 201.328) and established by a final rule in the *Federal Register* of November 18, 2016 (81 FR 81685 at 81694). Although we included corresponding changes and adjustments resulting from the final rule to the information collection approved under OMB control number 0910-0139 as it pertains to good manufacturing practice requirements and regulations in part 211 (21 CFR part 211), we did not make corresponding changes and adjustments to this information collection with regard to burden that may be associated with labeling requirements found in § 201.328 (81 FR 81685 at 81694).

We therefore request OMB approval for the information collection provisions found in 21 CFR part 201, subpart B (21 CFR 201.50 through 201.58) applicable to labeling requirements for prescription drugs, as well as labeling requirements established in 21 CFR part 201.328 with regard to the labeling of medical gas containers.

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 we regulate. We intend for 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 electronically disseminating up-to-date and comprehensive medication information to use in information systems that support patient care. The DailyMed makes current information about FDA-regulated products readily available to physicians, other health care practitioners, and

patients. In addition, manufacturers can use the new format for prescription drug labeling with electronic prescribing systems under development.

3. Use of Improved Information Technology and Burden Reduction

Manufacturers submit drug product labeling 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. Manufacturers electronically report these applications and associated submissions. 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 information collection in control no. 0910-0340 to account for burden attributable to over-the-counter labeling requirements.

5. Impact on Small Businesses or Other Small Entities

This information collection does not impose undue burden on small entities. Manufacturers provide labeling information to FDA as part of the review for drugs and biological products application review process. We help small businesses by providing Agency guidance on our website and through our small business assistance staff in our Center for Drug Evaluation and Research.

6. Consequences of Collecting the Information Less Frequently

This information collection schedule is consistent with the statutory and regulatory requirements.

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

No special circumstances apply to this collection of information.

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

FDA published a 60-day notice for public comment in the *Federal Register* of September 7, 2021 (86 FR 50134); no comments were received.

9. Explanation of Any Payment or Gift to Respondents

We do not provide payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure the appropriate identification and handling of the information FDA is collecting. We conclude that personally identifiable information (PII) is collected in the context of the subject individuals’ professional capacity and the FDA-related work performed for their employer (for example, the point of contact at a regulated entity). The PII is submitted using Form FDA 356h (Application to Market a New or Abbreviated New Drug for Human Use <https://www.fda.gov/media/86080/download>), and includes the name, work email address, work telephone numbers, work address, and work fax telephone number for the primary contact at a business. Other information FDA receives through Form 356h includes potentially identifying work information including job title, credentials, and the country of the contact.

Under the Freedom of Information Act (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 to 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. 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

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

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hourly Burden Estimate.

Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Labeling requirements for prescription drugs; §§ 201.56 and 201.57	414	1.326	549	3,349	1,838,601
Labeling of medical gas containers; § 201.328	260	1,663	432,380	0.17 (10 mins.)	73,505
Total			432,929		1,912,106

We assume new drug product and biological product applicants must: (1) design and create prescription drug labeling containing “*Highlights*,” “*Contents*,” and “*Full Prescribing Information*”; (2) test the designed labeling (for example, to ensure that the designed labeling fits into carton-enclosed products); and (3) submit it to FDA for approval. Based on our experience with the information collection, we estimate 414 applicants will prepare an average of 549 prescription drug labels and assume it will require 3,349 hours to design, test, and submit to FDA as part of a new drug application or a biologics license application. Similarly, new medical gas containers must meet applicable requirements found in part 211, as well as specific labeling requirements in § 201.328. We estimate that 260 respondents will incur burden for the design,

testing, production, and submission of labeling for new medical gas containers as required under § 201.328 and assume an average of 10 minutes (0.17) is required for these activities.

12b. Annualized Cost Burden Estimate.

We assume an average pharmaceutical industry wage rate of \$75.00 per hour to prepare and submit to FDA the required information. We multiplied \$75.00 by the total burden hours above 1,912,106 and estimate a cost to respondents of \$143,407,950.

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

There are no capital or operating and maintenance costs associated with the 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 OMB control numbers 0910-0001 (NDAs) and 0910-0338 (BLAs).

15. Explanation for Program Changes or Adjustments

The information collection reflects changes and adjustments. We are accounting for burden that may be associated with requirements found in 21 CFR § 201.328 applicable to the labeling of medical gas containers not previously included. This results in an overall increase to the collection by 432,388 responses and 653,199 hours annually.

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

We will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the certification are associated with this information collection.