UNITED STATES FOOD & DRUG ADMINISTRATION

Nonprescription Drug Product With An Additional Condition For Nonprescription Use

OMB Control Nos. 0910-0001 and 0910-0340 - Revision
RIN 0910-AH62

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This request is being submitted in support of agency rulemaking in accordance with 5 CFR 1320.11. Agency regulations regarding the approval of new drug applications are codified in 21 CFR part 314; regulations regarding labeling for drugs are codified in 21 CFR part 201, and include regulations governing the format and content of labeling for nonprescription products in subpart C. The regulations amend the new drug application (NDA) and abbreviated new drug application (ANDA) regulations to establish requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU). The regulations also amend labeling requirements applicable to these products. The final rule establishes the requirements for a nonprescription drug product that has an additional requirement that an applicant must implement to ensure appropriate self-selection or appropriate actual use, or both, by consumers without the supervision of a healthcare practitioner. We therefore request OMB approval of the information collection associated with the final rule.

2. Purpose and Use of the Information Collection

The final rule is intended to increase options for applicants to develop and market of safe and effective nonprescription drug products, which could improve public health by broadening the types of nonprescription drug products available to consumers. The action, if finalized, will codify requirements for a nonprescription drug product with an ACNU. These regulations are also intended to establish an effective system for FDA's surveillance of marketed drugs. Without the information provided by respondents regarding the drug products they seek to market, we would not be able to adequately protect the public health by assuring their safety and efficacy.

For nonprescription products with an ACNU, the regulations will provide the information necessary for FDA to approve an NDA or ANDA for a nonprescription drug for which labeling alone is not sufficient to ensure that the consumer can appropriately self-select or use a drug product safely and effectively in a nonprescription setting. FDA approval of an NDA or ANDA for a nonprescription drug product with an ACNU will improve public health by expanding the types of drug products consumers can access and use over-the-counter that would otherwise only be available by prescription.

3. Use of Improved Information Technology and Burden Reduction

Electronic submission of the information is required under 21 CFR part 314 for approval of nonprescription drug products with ACNU.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Upon finalization of the rule, the information collection provisions will revise currently approved OMB Control Nos. 0910-0001 (Applications for FDA Approval to Market a New Drug) and 0910-0340 (Format and Content Requirements for Over-the-Counter Drug Product Labeling).

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection poses undue burden on small entities. At the same time, FDA has established various agency components to assist small businesses in complying with our regulations. Contact information may be found on our website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

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

No special circumstances are applicable to this information collection.

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

In accordance with 5 CFR 1320.11, FDA is providing a 30-day public comment period on the information collection. In the proposed rule, we sought comments on our analysis. We did not receive any comments that were specific to our numeric hour burden estimates. However, we received numerous comments on the provisions of the proposed rule having to do with proposed requirements for applications, postmarketing reports, and labeling. The final rule contains comment summaries and responses for these comments in section V. E and F, and I through M. For the final rule, we did not change our numeric hour burden estimates from those reported in the proposed rule.

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts associated with this rule.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII) or other data of a personal nature, it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their

employer (e.g., point of contact at a regulated entity). The PII submitted via Form 365h Application to Market a New or Abbreviated New Drug or Biologic for Human Use, is name, work mailing address, work email address, work telephone, fax number, U.S. license number and DUNS number.

We have determined that the PII collected is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, the contractor or FDA do not use name or any other personal identifier to routinely retrieve records from the information collected.

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)(1-9)). 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

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Estimated Annual Reporting and Recordkeeping Burden

We estimate the burden of this information collection as follows:

Table 1.--Estimated Annual Reporting Burden; OMB Control No. 0910-0001[1]

Information Collection Activity; 21 CFR part 314 (Application for FDA Approval to Market a New Drug)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (Hours)	Total Hours
Submission of separate application for nonprescription drug product with an ACNU (§ 314.56(b) and (c)	6	1	6	320	1,920
Other postmarketing reports; submission of each individual consumer affected by a failure in implementation of an ACNU; 314.81	6	25	150	40	6,000
TOTAL			0		0

[1] There are no capital, or operating or maintenance costs associated with the information collection.

NDA and ANDA Submissions

Based on our experience with information collection associated with current NDA and ANDA submissions, we estimate six applications for a nonprescription drug product with an ACNU will be submitted annually. Based on Broad Agency Announcement proposals that set forth the number of hours anticipated to produce study reports for submission to us, we assume it will take an average of 320 hours per application for both NDA and ANDA applicants to prepare and submit the information required for applications for nonprescription drugs with an ACNU (in addition to meeting the general NDA or ANDA requirements under §§ 314.50 and 314.94, already approved in OMB Control No. 0910-0001).

Reports of a Failure in Implementation of an ACNU

We estimate six respondents will submit 25 reports each to FDA for individual failure in implementation of an ACNU under § 314.81(b)(3)(v). We assume an average of 40 hours per response for each applicant, for a total of 6,000 hours annually.

Table 2.--Estimated Annual Recordkeeping Burden; OMB Control No. 0910-0001[1]

Information Collection; 21 CFR part 314 (Applications for FDA Approval to Market a New Drug)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (Hours)	Total Hours
Requirements for failures in implementation of an ACNU (§ 314.81(b)(3)(v)(d))	6	25	150	8	1,200

[1] There are no capital, or operating or maintenance costs associated with the information collection.

Based on our experience with postmarket recordkeeping requirements, we assume an average burden of 8 hours of recordkeeping for each report and therefore have calculated 1,200 hours annually.

Table 3.--Third-Party Disclosure Burden; OMB Control No. 0910-0340[1]

Information Collection Activity; 21 CFR part 201, subpart C (Format and Content Requirements for Over-the-Counter Drug Product Labeling)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Disclosure of information on the principal display panel or within Drug Facts Labeling; 201.66 (including)g statements specified in § 201.130(a)(1) and (2)	6	1	6	15	90
ACNU statement; (§ 201.67)	6	1	6	9	54
TOTAL			0		0

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

Labeling for Nonprescription Drugs with an ACNU

Based on our experience with NDA and ANDA submissions, we estimate six respondents will each submit an application for a nonprescription drug product with an ACNU, each becoming subject to all nonprescription labeling regulations in (21 CFR 201, subpart C, including the requirements for statements of identity and net contents (§§ 201.61 and 201.62) which appear on the principal display panel (PDP) (defined by § 201.60), and the Drug Facts label (DFL) requirements of § 201.66, as part of which the respondents must also include (where applicable) labeling to satisfy sodium, calcium, magnesium, and potassium labeling requirements (§§ 201.64, 201.70, 201.71, and 201.72), and the statements required by §§ 201.130(a)(1) and (a)(2). These products may also have additional labeling beyond the DFL requirements (§ 201.67(c)(2)).

Estimating six respondents will expend 1 hour annually to comply with PDP and DFL labeling requirements under § 201.67(c)(1), and assuming each disclosure will require 15 hours, we calculate a total of 90 hours annually. Additionally, we estimate six respondents will each submit one application for a nonprescription drug product with an ACNU that contains additional labeling requirements, for a total of six annual responses. Based on our experience with nonprescription labeling requirements, we assume an average burden per response of 9 hours, for a total of 54 hours annually.

12b. Annualized Cost Burden Estimate

We estimate reduction in access costs to consumers who could transfer from a prescription to a nonprescription drug product with an ACNU. Our primary estimate for this item is $33.62 per consumer per purchase with a range of $0 to $67.23. We also quantify the value of the potential reduction in the number of meetings with applicants that will occur during the approval process. This estimate includes benefits to us and industry. Our primary estimate is $68,773.11 per applicant with a range of $56,332.65 to $81,763.56.

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

There are no capital costs and operating and maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

Costs of the information collection will be absorbed through existing resource allocations.

15. Explanation for Program Changes or Adjustments

The information collection will expand the scope of OMB Control Nos. 0910-0001 and 0910-0340 to provide for new regulatory provisions. Estimated burden from the corresponding information collection will result in an adjustment to OMB Control No. 0910-0001 by 9,120 hours and 306 responses annually; and an adjustment to OMB Control No. 0910-0340 by 144

hours and 12 disclosures annually.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

There are no exceptions to the certification.