

UNITED STATES FOOD & DRUG ADMINISTRATION

RIN 0910-AH62: *Nonprescription Drug Product With An Additional Condition For Nonprescription Use*

OMB Control No. 0910-0001 – Revision

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA); Food and Drug Administration (FDA, the agency, us or we) regulations; agency and industry program performance goals established in accordance with user fee authority; and associated guidance. Section 505 of the FFDCA (21 U.S.C. 355) governs procedures and requirements for the submission and review of applications and abbreviated applications to market a new drug, including amendments, supplements, and postmarketing reports to and for those applications. We have promulgated regulations in 21 CFR part 314 setting forth content and format requirements for new drug applications (NDAs) and abbreviated new drug applications (ANDAs), that include associated recordkeeping and disclosure requirements. Both the FFDCA and our implementing regulations explain a sponsor's responsibility to provide us with information needed to make a scientific and technical determination as to whether a product is safe and effective for use. For more information regarding new drug applications generally visit our website at: www.fda.gov/drugs/types-applications/new-drug-application-nda.

We are revising the information collection to support agency rulemaking (0910-AH62) that establishes requirements for a nonprescription drug product with an “*additional condition for nonprescription use* (ACNU)” at 21 CFR 314.56. The rulemaking also amends labeling requirements applicable to these nonprescription drug products with an ACNU, and establishes that applicants of nonprescription drug products implement required steps to ensure appropriate compliance with the regulatory requirements.

2. Purpose and Use of the Information Collection

Section 505 of the FFDCA requires that a new drug may not be marketed unless the manufacturer provides FDA with scientific evidence that the drug is both safe and effective for human use. For nonprescription products with an ACNU, the new requirements will provide 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

Although waivers may be granted, we encourage the electronic submission of information as set forth in 21 CFR part 314. We have developed several resources, available at <https://www.fda.gov/drugs/types-applications/new-drug-application-nda>, to assist respondents with the respective requirements to assist respondents with both technical and substantive elements of submission. All forms are available electronically and are submitted through our [Electronic Systems Gateway \(ESG\)](#). Consistent with regulations in 21 CFR 314.445, we have also developed and issued guidance documents to assist respondents in complying with regulations in part 314. These guidance documents and others are available at FDA's web site <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. We reference relevant information collections approved in our current inventory as appropriate throughout this document.

5. Impact on Small Businesses or Other Small Entities

The regulations at 21 CFR Part 314 do not provide exemptions for small businesses. However, 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>. Additionally, and as mentioned above, FDA's Center for Drug Evaluation and Research (CDER) has issued guidance on a variety of topics associated with new and abbreviated drug applications. These documents are developed to assist respondents with the regulatory requirements and are available online.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory requirements set forth in the FFDCa, applicable agency regulations, and FDA and Industry user fee performance goals.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5(d)(2)

There are the following special circumstances relating to the information collection: (1) sections of 21 CFR 314 require reporting in less than 30 days – these are postmarketing reports and expedited notification to FDA and are necessary to determine as soon as possible whether a threat to the public health exists that warrants immediate regulatory action; (2) more than an original and 2 copies of a submission is required (e.g., four copies of draft labeling or 12 copies of final printed labeling) in order to permit concurrent (and, consequently, quicker) review of the applications by multiple reviews; (3) although applicants are required to submit proprietary, trade secret, and other confidential information, this information is protected under FDA regulations and the FFDCa (see Q-10 below); and (4) the specific format and content requirements for application submissions are necessary to ensure complete submissions (and reduce the need for time-consuming resubmissions) and to assist FDA in efficient reviews.

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

In the *Federal Register* of June 8, 2022, FDA published a proposed rule entitled “*Nonprescription Drug Product With an Additional Condition for Nonprescription Use*” (87 FR 38313), and invited public comment in accordance with 5 CFR 1320.11. Although we did not receive comments specifically addressing our hourly burden estimates, we received numerous substantive comments on the provisions of proposed regulation. In the *Federal Register* of December 26, 2024 (89 FR 105288), we published a final rule containing comment summaries and responses to comments in sections V.E and F, and I-M. No adjustment was made to our burden estimate in response to public comment and we retain those proffered in the proposed rule.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

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.

The Freedom of Information Act (FOIA)

Under 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.

The Privacy Act of 1974

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The regulations in 21 CFR 314 include specific data elements to be included in an application. The regulations apply individually and comprehensively as the application may require. The regulations in **Subpart A** (§§ 314.1 through 314.3) set forth general provisions and explain their purpose and scope, while regulations in **Subparts B and C** – Applications and Abbreviated Applications (§§ 314.50 through 314.99) set forth content and format requirements for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) respectively. The regulations include requirements for the submission of specific data elements along with patent information, pediatric use information, supplements and amendments, proposed labeling, and specific postmarketing reports (PMRs). Respondents to the information collection are sponsors of these applications. While product marketing application (NDAs and ANDAs) information is reported to FDA, we have characterized the activities as recordkeeping requirements noting such requirements to include the tasks of reporting and disclosing the information, consistent with 5 CFR 1320.3(m).

Other regulations may also apply. For example, as referenced in Q-1, information pertaining to bioavailability and bioequivalence requirements as established in 21 CFR part 320, and information pertaining to radiopharmaceutical safety and effectiveness information as established in 21 CFR part 315, may also be included in the application. Similarly, general labeling provisions set forth in 21 CFR part 201 are required elements of the application. Unless otherwise indicated, we include in our estimate the time we believe necessary for reviewing and providing the information.

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden¹

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	Avg. 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
Submission of ACNU failure reports; (§ 314.81(b)(3)(v))	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 Burden¹

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
Recordkeeping 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. The applicant must maintain for a period of 10 years, the records of all reports of ACNU failures and associated adverse drug experiences known to the applicant, including raw data and any correspondence relating to a report of an ACNU failure.

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 or operating and maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

FDA has allocated 835 FTEs to reviewing submissions under 21 CFR 314. Where the cost of each FTE is approximately \$325,348 (fully-loaded), the total cost burden to the Federal Government is estimated at \$271,665,580. These costs are supplemented by industry submission of application and program user fees for prescription and generic drug applications and approved products.

15. Explanation for Program Changes or Adjustments

As a result of the rulemaking, we have adjusted the burden for the information collection by 9,120 hours and 306 responses annually.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish tabulated results of these information collection requirements.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of the OMB Expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.