

United States Food and Drug Administration

Importation of Prescription Drugs

OMB Control No. 0910-0888

SUPPORTING STATEMENT

EXTENSION

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us, or we) implementation of section 804(b) through (h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384(b) through (h)) and applicable regulations in 21 CFR part 251, which provide for the importation of certain prescription drugs shipped from Canada. The purpose of section 804 of the FD&C Act is to reduce the cost of covered products to American consumers without imposing additional risk to public health and safety. The regulations in 21 CFR part 251 set forth procedures that Section 804 Importation Program Sponsors (SIP Sponsors) must follow when submitting plans to implement time-limited programs to begin importation of drugs from Canada. The regulations also establish criteria for FDA review and authorization of a SIP Proposal or supplemental proposal. Additionally, the regulations set forth requirements for eligible prescription drugs and requirements for entities that engage in importation of eligible prescription drugs. Finally, the regulations provide that eligible prescription drugs that meet certain requirements are exempt from section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)).

Therefore, we request Office of Management and Budget (OMB) approval of the information collection associated with importation of prescription drug requirements in the applicable regulations.

2. Purpose and Use of the Information Collection

The information collection provisions are designed to facilitate programs for importation of products that pose no additional risk to the U.S. public's health and safety and will result in a significant reduction in the cost of covered products to American consumers. We will use the information collected to review SIP Proposals, including to assess supply chains.

A SIP can be co-sponsored by a State, Indian Tribe, pharmacist, or wholesale distributor. An Importer that is a wholesale distributor or pharmacist licensed in the United States will buy eligible prescription drugs directly from a "foreign seller" in Canada which purchases the drugs directly from the manufacturer. This information collection will be used by the private sector, State and Tribal Governments (SIP Sponsors), and the Federal Government to maintain the integrity of supply chains, protect the public from interruptions of supply or diversion of these prescription drugs, and ensure that the drugs are authentic, not degraded, and meet established specifications and standards.

Description of Respondents: Respondents to the collection of information are SIP Sponsors (States or Indian Tribes, or in certain future circumstances pharmacists or wholesale distributors,

and any cosponsor(s)), importers (pharmacists or wholesale distributors), and manufacturers of eligible prescription drugs.

3. Use of Improved Information Technology and Burden Reduction

FDA estimates that 100 percent of the respondents will use electronic means to fulfill the Agency's requirements or requests. A State or Indian Tribe that seeks to implement a SIP must submit a proposal to FDA in electronic format via email to SIPDrugImportsandRFP@fda.hhs.gov. An importer will submit a pre-import request to FDA via email to SIPDrugImportsandRFP@fda.hhs.gov.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection poses undue burden on small entities.

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

There are no special circumstances relating 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 1320.8(d), FDA published a 60-day notice inviting public comment in the *Federal Register* of June 8, 2023 (88 FR 37549).

We received one comment communicating that we had revised our burden estimates from those found in the final rule that issued October 10, 2020 (85 FR 62094). The comment also suggested that our figures underestimated burden associated with individual provisions established by part 251 although no alternative figures were proffered. We note also, that both FDA and respondents continue to carry out certain provisions in part 251, including activities related to the information collection elements. The comment also appeared to question how FDA derived its count of respondents included in the information collection. In this regard, we note that the scope of the information collection is set forth in 21 CFR 251.1. We appreciate all comments but refrain from making further modifications to our estimate until we have more experience with the implementation of the information collection.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

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.

The Privacy Act of 1974

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals’ professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted includes point of contact name, work phone number, work address, and work email address. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act

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

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

FDA estimates the burden for the information collection as follows:

Table 1.—Estimated Annual Recordkeeping Burden

21 CFR Section 251; Information Collection Activity	No. of Respondents	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Record	Total Hours
Subpart B; SIP Proposals and Pre-Import Requests	40	1.5	60	72 hours	4,320
Subpart C; certain requirements for importation programs	40	1	40	43 hours	1,720
TOTAL					80

We assume burden attributable to the information collection tasks will be distributed among respondents. As noted in the previous submission, FDA estimates that there will be 10 SIP Sponsors requiring 360 hours each to research, prepare, and administer requirements annually; 10 Pre-Import Requests requiring 24 hours each annually; and 20 manufacturers also requiring 24 hours each annually to participate in the program. In addition, FDA estimates that a recordkeeping burden of 52 hours will be imposed annually on the 10 SIP Sponsors, and a

recordkeeping burden of 24 hours will be imposed annually on each of the 10 Importers and the 20 manufacturers. The 20 manufacturers anticipated to participate in the program will also incur an estimated burden of 24 hours each for copying and providing records to SIP Sponsors and Importers of foreign transactions.

A SIP sponsor will submit a SIP proposal that includes, among other things, information about the SIP Sponsor and the SIP Sponsor's importation plan. In addition, SIP Sponsors must provide FDA with data and information on the drugs the SIP proposes to import and on the SIP's cost savings to the American consumer.

Importers have a number of responsibilities related to submitting a Pre-Import Request to FDA, screening eligible prescription drugs, safety reporting, and arranging for importing, testing, and relabeling. A pre-import request will identify information regarding the importation, relabeling of the Canadian products, and relevant information necessary to evaluate whether the products meet established specifications and standards.

Manufacturers will provide information needed to ensure that the drugs are authentic, not degraded, and in compliance with established specifications and standards.

12b. Annualized Cost Burden Estimate

The total estimated cost burden for this collection of information is based upon performing a similar position in the government as private industry. The cost to respondents is estimated to approach the hourly cost of a GS-10, step 5 worker, or \$31 per hour. Therefore, the cost associated with this collection is \$187,240 (6,040 burden hours x \$31.00).

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

As we continue to implement this program, we assume, based on estimated costs for other import program ICRs and adjusted based on a ratio of covered respondents, the annual cost to the Federal government to be \$163,094.40.

15. Explanation for Program Changes or Adjustments

We have established a web page at <https://www.fda.gov/about-fda/reports/importation-program-under-section-804-fdc-act> to communicate news and information about FDA efforts to implement the Section 804 Importation Program. To date, however, no SIP proposals have been authorized since publication of the final rule on October 1, 2020 (85 FR 62094). We have therefore retained figures from the previous information collection approval.

We assume burden attributable to the required retention, reporting and disclosure of records pertaining to these information collection activities will be distributed among respondents for an average of 100 responses and 6,040 hours 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

FDA 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.