UNITED STATES FOOD & DRUG ADMINISTRATION

Federal Food, Drug, and Cosmetic Act Section 804:
Personal Importation of Prescription Drugs
21 CFR part 251

OMB Control No. 0910-NEW
RIN-AI45

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA, the agency, us or we) is promulgating regulations pursuant to section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 USC 384) to allow importation of certain prescription drugs from Canada. The proposed regulations are to be codified at 21 CFR part 251 (21 CFR 251). Under the proposed rule, FDA would authorize Section 804 Importation Programs (SIPs), which would be overseen by States or certain other governmental entities (SIP Sponsors), to import certain prescription drugs from Canada. SIP sponsors must submit a 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 imports and on the SIP's cost savings to the American consumer. Importers would have a number of responsibilities related to submitting a Pre-Import Request to FDA, screening eligible prescription drugs and arranging for importing, testing, and relabeling. Manufacturers would provide information needed to authenticate eligible prescription drugs. Accordingly, we are requesting OMB approval of the proposed information collection provisions contained in the proposed rule entitled "*Importation of Prescription Drugs*," and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The proposed regulations are intended to enable American consumers to benefit from the lower prices charged for certain prescription drugs in Canada. The information collection provisions of the proposed rule are designed to facilitate programs for importation of products that pose no additional risk to the US public's health and safety, and will result in a significant reduction in the cost of covered products to American consumers. The information collected would be used by FDA to review SIP program proposals and extension requests, including to assess supply chains. Respondents would include SIP Sponsors (State, tribal, or territorial governmental entities), Importers (pharmacists or wholesalers), and manufacturers of eligible prescription drugs.

This information collection would be used by the Private Sector (Importers and manufacturers); State, Local or Tribal Governments (SIP Sponsors); and the Federal Government to maintain the integrity of the products to be imported through the supply

chain, demonstrating them to be safe and effective as required under the FD&C Act and to protect the public from interruptions of supply or diversion of these safe and effective prescription products.

3. Use of Improved Information Technology and Burden Reduction

We estimate 100% of the respondents will use electronic means to fulfill the agency's requirements or requests. The proposed rule states that a SIP Sponsor that seeks to implement a SIP to import prescription drugs from Canada must submit a proposal to FDA in electronic form to FDA's Electronic Submissions Gateway (ESG) or to an alternative transmission point identified by the agency. In addition, each importer approved under a SIP sponsor will submit a pre-import request to FDA identifying information regarding the importation, relabeling of the Canadian products, and relevant documentation of information necessary to evaluate whether the imported products meet FDA requirements for manufacturing quality and safety.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of any duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection will not have a significant economic impact on a substantial number of small entities or pose an undue burden on small entities. Contracts resulting from the proposed rule are voluntary and will depend on the scope and scale of approved and implemented SIP Proposals, the details of which are unknown.

Under the Regulatory Flexibility Act, FDA analyzes regulatory options that would minimize any significant impact on small entities. FDA also assists small businesses in complying with regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

Respondents will respond to the information collection annually and quarterly. There are no legal obstacles to reduce the burden.

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

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection

requirements of the proposed rule that published in the Federal Register of December 23, 2019 (84 FR 70796).

9. Explanation of Any Payment or Gift to Respondents

There is no remuneration associated with the proposed information collection.

10. Assurance of Confidentiality Provided to Respondents

We have consulted with our Privacy Office to identify potential risks associated with privacy information that may be handled by or on behalf of FDA in administration of this information collection. Although personally identifiable information (PII) would be collected, it is not subject to the Privacy Act of 1974 and therefore the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected. We have also minimized the PII to be collected to protect the privacy of the individuals.

11. Justification for Sensitive Questions

The information collection does not include questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

Type of Information Collection Activity/ Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
SIP Sponsor 251.3; 251.8; 251.14 - SIP Proposal Submission Requirements; 251.18 - Post Importation Requirements; 251.19 - Reports to FDA	10	1	10	360	3600
Importer 251.5; 251.12; 251.13; 251.17 - Pre-Import Request and Importation Requirements	10	1	10	24	240
Manufacturer 251.16 Lab Testing Requirements	20	1	20	24	480
Total					4320

Table 2.--Estimated Annual Recordkeeping Burden

Type of Information Collection Activity/ Respondent	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours
SIP sponsor 251.8 - Modification or Extension of Authorized Importation Programs	10	1	10	52	520
Importer 251.14(d) – Supply Chain Security Requirements; 251.17 - Importation Requirements; 251.18 Post Importation Requirements	10	1	10	24	240
Manufacturer 251.14(b) - Supply Chain Security Requirements	20	1	20	24	480
Total					1240

Table 3.--Estimated Annual Third-Party Disclosure Burden

Type of Information Collection Activity/ Respondent	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure	Total Hours
Manufacturer 251.14(b) - Supply Chain Security Requirements	20	1	20	24	480

12b. Annualized Cost Burden Estimate

SIP Sponsors would face costs to prepare proposals, implement approved SIPs, and produce SIP reports and records. SIPs may offer cost savings to patients, as well as participating wholesale drug distributors, pharmacies, hospitals, and third-party payers. U.S. drug manufacturers may face lost U.S. sales (which transfer to Importers and U.S. consumers) as well as certain compliance costs if their drugs are imported into the United States from Canada. We lack sufficient information about the likely size and scope of SIP programs and about the specific drug products that may become eligible for importation and which SIP eligible products are produced by U.S. drug manufacturers to estimate the present and annualized values of the costs of the rule.

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

We lack sufficient information to estimate potential capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Costs to the Federal government would be absorbed through existing resource allocations and therefore we estimate no costs at this time.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The agency has no plans for publication of information from this information collection.

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.