

UNITED STATES FOOD AND DRUG ADMINISTRATION

Section 804 Importation Program Proposals – 21 CFR part 251

OMB Control No. 0910-0888

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SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection enables the Food and Drug Administration (FDA, the agency, us or we) to implement section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Specifically, section 804(b) through (h) of the FD&C Act (21 U.S.C. 384(b) through (h)) allows importation of certain prescription drugs shipped from Canada, and we have promulgated governing regulations in 21 CFR part 251. We are taking this action to achieve a reduction in the cost of covered products to the American consumer while posing no additional risk to the public's health and safety.

As explained in our final rule entitled, “*Importation of Prescription Drugs*,” which published in the Federal Register on October 1, 2020 (85 FR 62094), we intend to implement this program through time-limited Section 804 Importation Programs (SIPs), which will be authorized by FDA and managed by States or Indian Tribes, or in certain circumstances by pharmacists or wholesale distributors (SIP Sponsors). 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.

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

Regulations in 21 CFR part 251 establish procedures SIP sponsors must follow, including information collection provisions, regarding the format, content, timing of, and action on submissions. Accordingly, we request OMB approval of the information collection provisions associated with section 804 of the FD&C Act and our implementing regulations in 21 CFR part 251, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The information collection provisions are designed to facilitate programs for importation of covered products that pose no additional risk to the U.S. public's health and safety, and are intended to result in a reduction in the cost to American consumers. The information collected, will be used to review SIP Proposals and extension requests, including to assess supply chains. Respondents include SIP Sponsors (States and Indian Tribes), Importers (pharmacists and wholesalers), and manufacturers of eligible prescription drugs. Information collected also identifies the section 804 serial identifier (SSI), unique to each package or homogenous case of product and links the SSI to manufacturing records and shipments intended for the Canadian market.

This information collection will be used by the Private Sector (Importers and manufacturers), 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, are not degraded, and meet established specifications and standards.

Post-importation requirements also include SIP Sponsors providing FDA with data and information about the execution of the SIP, including cost savings to the American consumer, return plans, and a written recall plan describing procedures to perform a recall of the products, if required, and specifying who is held responsible for performing those return or recall procedures for protection of the American public.

3. Use of Improved Information Technology and Burden Reduction

We estimate 100% of respondents will use electronic means to fulfill the agency's requirements or requests. Regulations require that a State or Indian Tribe seeking to implement a SIP must submit a proposal to FDA in electronic format via FDA's Electronic Submissions Gateway (ESG) or to an alternative transmission point identified by FDA. In addition, an Importer will submit electronically a pre-import request to FDA identifying information regarding the importation, relabeling of the Canadian products, and relevant information necessary to evaluate whether the products meet established specifications and standards.

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. Agreements resulting from the rule are voluntary and will depend on the scope and scale of authorized and implemented SIPs, 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), we published a proposed rule in the Federal Register of December 23, 2019 (84 FR 70796) inviting public comment on the information collection. A discussion of all comments may be found in the preamble of our final rule (85 FR 62094), noting that those below were found relevant to the information collection:

(Comment 62) Several comments ask FDA to limit requirements that they characterize as duplicative or redundant, citing adverse event reports, individual case safety reports (ICSRs), and recall requirements. In addition, one comment suggests that patients might not know whom to contact regarding an adverse event or a question about medication.

(Response 62) FDA declines to make substantive changes in response to these comments. We have made some minor revisions from the provisions in the NPRM for clarity. For example, in one instance we have revised the wording to align with existing comparable requirements in 21 CFR 314.80 (under § 251.18(d) (9), an Importer must “develop” written procedures to meet their obligations under that subpart because this encompasses the requirement to “maintain” and “follow” such written procedures), but such clarifications do not change FDA’s interpretation of the scope of existing responsibilities under § 314.80 or other existing safety reporting requirements.

We do not believe the reporting requirements in the final rule are duplicative or redundant. The rule requires an Importer to establish and maintain records and submit to FDA and the manufacturer reports of all adverse events associated with the use of the drug products it imports under section 804 of the FD&C Act and this final rule. An individual case safety report (ICSR) is a description of an adverse event related to an individual patient or subject. The final rule outlines when and how an Importer must submit ICSRs for domestic adverse events, and follow up reports, to FDA and the manufacturer. As described in the NPRM (84 FR 70796 at 70821), these reports will aid the manufacturer in its pharmacovigilance efforts, and it will provide FDA with information that may be relevant to its review of SIP

Proposals and Pre-Import Requests as well as to its oversight of drugs imported under section 804 of the FD&C Act and section 804 in general. In the event of a recall, Importers must, upon request by FDA, provide to FDA the transaction history, information, and statement, as those terms are defined in section 581(25), (26), and (27) of the FD&C Act, for the recalled drugs. We have clarified in the final rule that, in the event of a recall, Foreign Sellers must also provide certain transaction information to FDA upon request.

(Comment 64) Several comments request clarification regarding recall responsibilities. One comment says that the timeframe for adverse event reporting could lead to significant delays in recalls.

(Response 64) The rule requires that each SIP proposal include a recall plan that explains how the SIP Sponsor will obtain additional recall or market withdrawal information, such as by obtaining recall information from an Importer, and how the SIP Sponsor will ensure that recall or market withdrawal information is shared among the SIP Sponsor, the Foreign Seller, the Importer, and FDA, and provided to the manufacturer. In addition, the rule requires that each SIP must have a written recall plan that describes the procedures to perform a recall of the product and specifies who will be responsible for performing the procedures. The recall plan must cover recalls mandated or requested by FDA and recalls initiated by the SIP Sponsor, as well as recalls in Canada or the United States initiated by a drug's manufacturer that implicate a drug imported under a SIP, with which the Foreign Seller or Importer must cooperate. If FDA or any participant in a SIP determines that a recall is warranted, the SIP Sponsor must effectuate the recall in accordance with its written recall plan. We have revised the rule to clarify an Importer's and a Foreign Seller's responsibilities in a recall. We do not believe that the timeframes for adverse event reporting, which are consistent with other FDA requirements for adverse event reporting, would lead to significant delays in effectuating a recall.

Although we have considered the comments and made the revisions discussed in our final rule, we have made no adjustments to our burden estimate. However, we note an inadvertent typographical error in Table 1 upon publication. We have included correct figures here.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payments or gifts for participating in this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to identify potential risks to the privacy information that may be handled by or on behalf of FDA in the performance of this information collection. Our analysis finds that personally identifiable information (PII) or information of a personal nature is being collected. The PII collected includes names, company names, addresses, email addresses, and telephone numbers. 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). Information obtained from SIPs would be authorized by FDA and overseen by SIP Sponsors that seek to import certain prescription drugs from Canada. SIP Sponsors must provide FDA with data and information on drugs imported under the SIP and on the SIP's cost savings to the American consumer.

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

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12 a. *Annualized Hour Burden Estimate*

Table 1.--Estimated Annual Reporting Burden¹

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	3,600
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; 251.18 - Post Importation Requirements	20	1	20	24	480
Total					4,320

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

Table 2.--Estimated Annual Recordkeeping Burden¹

Type of Information Collection Activity/ Respondent	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average 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; 251.18 - Post Importation Requirements	20	1	20	24	480
Total					1,240

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

Table 3.--Estimated Annual Third-Party Disclosure Burden¹

Type of Information Collection Activity/ Respondent	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Manufacturer 251.5 - Pre-Import Request; 251.14(b) - Supply Chain Security Requirements	20	1	20	24	480

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

12b. Annualized Cost Burden Estimate

SIP sponsors may incur costs to prepare proposals, implement approved programs, and produce records and program reports.

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

We believe there are no capital costs or operating and maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

Costs for initial implementation will be absorbed through existing resource allocations. We will consider future allocations upon review of the information collection.

15. Explanation for Program Changes or Adjustments

This is a new information 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.