4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2023-N-1189]**

# Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Importation of Prescription Drugs

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0888. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, PRAStaff@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

## Importation of Prescription Drugs

This information collection supports implementation of section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384), and applicable regulations in part 251 (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 part 251 set forth procedures 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)).

*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 wholesaler distributors), and manufacturers of eligible prescription drugs.

In the *Federal Register* of June 8, 2023 (88 FR 37549), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment communicating that we had revised our burden estimates from those found in the final rule that issued October 1, 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 § 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.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden[1]

| 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 | | | 100 | | 6,040 |

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

We assume burden attributable to the information collection tasks will be averaged and 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.

We have established a webpage 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, no SIP proposals have been authorized since publication of the final rule on October 1, 2020. 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.

Dated: October 10, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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