

In the **Federal Register** of March 23, 2026 (91 FR 13854), FDA published a 60-day notice requesting public

comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

FD&C act section; activity	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
User fee cover sheets, by type						
740(a)(1); Animal Drug User Fee cover sheet	FDA 3546	7	2	14	0.5 (30 minutes)	7
741(a)(1); Animal Generic Drug User Fee cover sheet	FDA 3728	22	2.4	53	0.5 (30 minutes)	26.5
Waiver and other requests, by type						
740(d)(1)(A); significant barrier to innovation	N/A	65	1	65	2	130
740(d)(1)(B); fees exceed cost	N/A	4	2	8	0.5 (30 minutes)	4
740(d)(1)(C); free choice feeds	N/A	4	1	4	2	8
740(d)(1)(D); minor use or minor species	N/A	78	1	78	2	156
740(d)(1)(E); small business	N/A	4	1	4	2	8
741(d)(1); minor use or minor species	N/A	3	1	3	2	6
Request for reconsideration of a decision	N/A	1	1	1	2	2
21 CFR 10.75; Appeal of a decision	N/A	1	1	1	2	2
Total						349.5

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

Our estimated burden for the information collection reflects an overall increase. We attribute this adjustment to an increase in the number of submissions we have received since our last evaluation. The total number of annual responses is based on the average number of submissions received by FDA in fiscal years 2022 to 2024. The estimated time we attribute to the hours per response is based on our experience with the various submissions and reflects the average burden we attribute to all respondents.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–17601 Filed 8–27–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–3240]

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) 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 September 28, 2026.

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: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–1244, PRASStaff@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—21 CFR Part 251

OMB Control Number 0910–0888—Extension

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). 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 for exempt eligible prescription drugs that meet certain requirements 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 April 16, 2026 (91 FR 20462) FDA published a 60-day notice soliciting comment on the proposed collection of information. We received one comment containing several topics. These issues included cost savings, patient risks, continuity of care, and product labeling. Because these topics are outside the scope of the 60-day notice, we decline to address

them here. The submitter also raised an issue regarding whether FDA had overestimated the burden associated with individual provisions established by part 251 (21 CFR part 251) (Section 804 Importation Program) although no alternative figures were given by the commenter. The commenter questions the number of recordkeepers and how FDA derived its count. In this regard, we note that the scope of the information collection is set forth in § 251.1 (21 CFR 251.1) and that our estimate of the number of recordkeepers is forward-looking and its baseline is

based on historical experience. Consistent with Executive Order 14273, FDA is taking steps to streamline and improve the section 804 importation program to make it easier for States to obtain authorization without sacrificing safety or quality in accordance with section 804 of the FD&C Act and FDA's implementing regulations. Additionally, in June 2026, FDA authorized another state's drug importation program proposal under section 804 of the FD&C Act. Consequently, we recognize that the number of respondents may fluctuate, especially during the initial

phases of the program's implementation. Because of this, the number of recordkeepers is based on our current best estimate of state involvement and interest.

We appreciate all comments on this information collection but refrain from making further modifications to our estimate until we gain more experience with its implementation. Upon receipt of such information FDA will revise our burden estimate accordingly in our next submission to OMB.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR section 251; information collection activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Subpart B; SIP proposals and pre-import requests	40	1.5	60	72	4,320
Subpart C; Certain requirements for importation programs	40	1	40	43	1,720
Total			100		6,040

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

We have established a web page at <https://www.fda.gov/drugs/importation-program-under-section-804-fdc-act/section-804-importation-program-policies-and-authorizations> to communicate news and information about FDA efforts to implement the SIP. We assume the burden attributable to the required retention, reporting, and disclosure of records pertaining to these information collection activities will be distributed among respondents at an average of 100 responses and 6,040 hours annually. Based on a review of the information collection since our last request for OMB approval we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: The National Health Service Corps Loan Repayment Programs OMB No. 0915–0127—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than October 27, 2026.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the

proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–9094.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: The National Health Service Corps Loan Repayment Programs, OMB No. 0915–0127—Revision.

Abstract: The National Health Service Corps (NHSC) Loan Repayment Program (LRP) was established to assure an adequate supply of trained primary care health professionals to provide services in Health Professional Shortage Areas (HPSAs) of the United States with the greatest need. The NHSC Substance Use Disorder Workforce LRP and the NHSC Rural Community LRP were established to recruit and retain a health professional workforce with specific training and credentials to provide evidence-based substance use disorder treatment in HPSAs. Under these programs, HHS agrees to repay the qualifying educational loans of selected primary care health professionals. In return, the health professionals agree to serve for a specified period of time in an NHSC-approved site located in a federally-designated HPSA approved by the Secretary of HHS for NHSC LRP participants.