APhA
American Pharmacists Association

June 15, 2026

[Submitted electronically to http://www.regulations.gov]

Grace R. Graham
Deputy Commissioner for Policy, Legislation, and International Affairs
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

RE: [Docket No. FDA-2026-N-3240] Agency Information Collection Activities; Proposed Collection; Comment Request; Importation of Prescription Drugs

Dear Deputy Commissioner Graham,

The American Pharmacists Association (APhA) appreciates the opportunity to provide FDA comments on the "Agency Information Collection Activities; Proposed Collection; Comment Request; Importation of Prescription Drugs," notice.

APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

Overview of FDA Notice

The notice states that "[t]his 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 "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 … [and] establish criteria for FDA review and authorization of a SIP proposal or supplemental proposal."[1] Additionally, it provides that "[t]he purpose of section 804 of the FD&C Act is to reduce the cost of covered

[1] Agency Information Collection Activities; Proposed Collection; Comment Request; Importation of Prescription Drugs, 91 Fed. Reg. 20462, 20463 (Apr. 16, 2026). Available at: https://www.federalregister.gov/d/2026-07421/p-18.

products to American consumers without imposing additional risk to public health and safety."[2]

APhA Position and Lack of Demonstrated Cost Savings

APhA has emphasized to FDA that the SIP policies pose significant risks to patient safety and continuity of care, and, as a result of additional steps in the supply chain, such as relabeling (twice) and laboratory testing requirements, it is highly unlikely that there will be significant cost savings for consumers. The need for additional track-and-trace, recall, and adverse-event reporting systems will further increase costs associated with the importation program, thereby negating any potential cost benefits to patients. Unknown, speculative, and unproven cost savings do not justify jeopardizing the integrity of the U.S. supply chain and patient safety. Current state SIP submissions do not include justification for annual cost savings in their analysis. APhA urges FDA not to approve any SIP proposals without a thorough cost analysis, including hard data supporting markup and cost-savings estimates.

Pharmacists' Role and Real-World Patient Risks

As the medication experts on every patient care team, pharmacists are essential in ensuring patient safety and optimal medication use. Pharmacists review and assess all available health information, screening for drug interactions and potential adverse events, to ensure that the medications their patients are receiving are safe and effective. Additionally, pharmacists field patient questions to promote adherence and improve patient outcomes. Pharmacists are seeing more patients present to their pharmacies with drugs acquired from other countries and online vendors. When patients come to pharmacies with medications from other countries or unknown sources, pharmacists recognize the potential harm patients may experience from counterfeit, illegitimate, or non-FDA-approved products and have limited resources to help patients ensure the products are genuine. By publicly promoting avenues for patients to secure drugs from other countries, like with the SIPs, FDA risks legitimizing this practice, and patients seek out cheaper medications, often from unlicensed and unregulated sources both within and outside the U.S. Accordingly, APhA urges FDA to abandon drug importation programs and proposals that threaten to weaken the integrity of the medication supply chain that Americans utilize for the safe and needed medications.

Continuity of Care Concerns

If drug importation programs are permitted or implemented, there will also be concerns related to continuity of care. Currently, Canadian pharmacists are only permitted to dispense medications prescribed by Canadian prescribers. Canada requires these regulations to ensure that physicians and pharmacists have established relationships with their patients and knowledge of their medical histories. Therefore, Americans would need to see a Canadian

[2] *Id.*

physician directly or have a co-signed prescription from a U.S. and a Canadian physician with whom the patient has an established relationship for the Canadian pharmacist to dispense any medications to the patient. Because of these regulations, American patients seeking to fill prescriptions at Canadian pharmacies will likely receive fragmented care as Canadian prescribers and pharmacists may not have access to their full health record, and their providers and pharmacists in the United States may not know about the medications they are receiving in Canada, increasing their risk for drug-drug interactions, adverse events, and duplicative or unnecessary medications.

Even if prescription drugs can be imported in bulk quantities directly from manufacturers or wholesalers in Canada, there will still be a continuity-of-care issue, as patients would only be able to acquire those drugs approved under the program in this manner, likely requiring them to go to multiple pharmacies. Given the lack of interoperability, the patient may be at increased risk of drug-drug interactions, adverse events, and duplicative or unnecessary medications if they fail to inform each of their pharmacists and other health care providers about all medications they are currently taking and that they are filling medications at other pharmacies or taking medications from other prescribers.

Product Labeling, Counterfeiting, and Patient Confusion

There are also other practical considerations that could put patient safety in question.

Prescription drug products created for the Canadian market may have different labeling than those intended for the U.S. market. These labeling changes may, on the surface, be minor, but could play a significant role if the drug is recalled. Additionally, differences in labeling of products made available to U.S. patients will exacerbate the current epidemic of criminals and fraudsters capitalizing on patients who do not understand the risks of buying medications from unlicensed and unregulated online vendors posing as pharmacies. Curbing these deceptive practices is critical, as "65% of U.S. adults falsely believe all websites offering online Rx/health services are reviewed/approved by FDA or state regulators."[3]

Overestimation of Recordkeeping Burden

Regarding the estimated annual recordkeeping burden, FDA estimates that there will be 40 recordkeepers for both Subpart B (SIP proposals and pre-import requests) and Subpart C (certain requirements for importation programs).[4] These estimates appear to significantly overestimate states' interest in such programs and the actual steps they have taken towards

[3] *ASOP Global Foundation 2025 U.S. Consumer Behavior Survey Executive Summary*, Alliance for Safe Online Pharmacies and ASOP Global Foundation (2025). Available at: https://asopfoundation.pharmacy/wp-content/uploads/2025/11/ASOP-Foundation-2025-Consumer-Behavior-Survey.pdf.

[4] Agency Information Collection Activities; Proposed Collection; Comment Request; Importation of Prescription Drugs, 91 Fed. Reg. 20462, 20464 (Apr. 16, 2026). Available at: https://www.federalregister.gov/d/2026-07421/p-20

their implementation. Currently, Florida's SIP is the only one authorized by FDA, yet it has not imported a single medication, despite receiving FDA authorization in 2024.[5] In fact, on May 6, 2026, FDA had to grant Florida its fourth authorization extension for an additional 6 months to begin implementing its SIP.[6] Within the Florida Agency for Health Care Administration's report to the Florida Legislature from 2025, the agency states that "implementation has been delayed due to significant resistance from pharmaceutical manufacturers, who ultimately control the supply chain for their products … [and] the Canadian government has expressed hesitation in supporting importation efforts out of fear that it will impact availability of medications for their citizens."[7] As such, APhA continues to strongly oppose the importation of prescription drugs from Canada into the United States.

While some other states have shown interest in establishing SIPs, if they follow Florida's timeline, their citizens are still years away from receiving any medication imported through the program, and their taxpayers will be on the hook for tens of millions of dollars in establishing a program that does not work. In Florida, legislation was passed in 2019, tasking the Florida Agency for Health Care Administration with locating vendors to establish a program to import prescription drugs from Canada for use by Florida residents in certain state-administered programs.[8] Florida submitted its SIP proposal to FDA in 2020 and was granted authorization in 2024 after additional FDA rulemaking and lawsuits. As noted above, since the 2024 authorization, FDA has had to extend this authorization four times, and no drugs have yet been imported,[9] while it is estimated that Florida has spent at least $50 million on the program.[10] At least six other states have passed legislation aiming to establish state drug importation programs, but only four of those six – Colorado, Maine, New Hampshire, and New Mexico – have submitted proposals to FDA.[11] Vermont has also submitted a concept letter to FDA following the passage of similar legislation in its state.[12] Accordingly, FDA's current estimates

---

[5] *Florida's Canadian Prescription Drug Importation Program*, Florida Agency for Health Care Administration (Oct. 2025). Available at: https://ahca.myflorida.com/content/download/27370/file/Canadian%20Prescription%20Drug%20Importation%20Program%20Q3.pdf.

[6] Letter to Shevaun Harris, Secretary, Florida Agency for Health Care Administration, from Sangeeta Chatterjee, Director, Office of Drug Security, Integrity, and Response, U.S. Food and Drug Administration (May 6, 2026). Available at: https://www.fda.gov/media/192846/download?attachment.

[7] *Florida's Canadian Prescription Drug Importation Program*, Florida Agency for Health Care Administration (Oct. 2025). Available at: https://ahca.myflorida.com/content/download/27370/file/Canadian%20Prescription%20Drug%20Importation%20Program%20Q3.pdf.

[8] *Id.*

[9] *Id.*

[10] Phil Galewitz, *Florida Gov. DeSantis' Canadian Drug Import Plan Goes Nowhere After FDA Approval*, KFF Health News (Nov. 22, 2024). Available at: https://kffhealthnews.org/health-care-costs/florida-gov-desantis-canadian-drug-import-plan-goes-nowhere-after-fda-approval/.

[11] *State Drug Wholesale Importation Programs*, National Conference of State Legislatures (May 7, 2024). Available at: https://www.ncsl.org/health/state-drug-wholesale-importation-programs.

[12] *Id.*

for both Subparts B and C appear to be overestimates of interest in and eventual application submissions for this program. As such, APhA encourages FDA to adjust these estimated recordkeeping burdens.

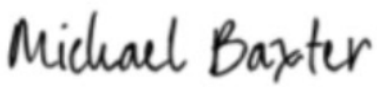
FDA may be basing these high estimates on new interest following their and the Department of Health and Human Services' presentations to the states in March.[13] However, even if states came away from these meetings with an interest in developing SIPs, they would likely still need to pass corresponding legislation and establish the requirements outlined in the forms, which is not a short process. Thus, APhA does not believe this to be a valid justification to estimate Subparts B and C at 40, and the estimated burdens should be updated to reflect the current overestimation.

Operational and Reimbursement Challenges in Pharmacies and for Patients

In addition, the commingling of FDA-approved and imported versions in the marketplace will disrupt pharmacy operations and cause confusion in product selection, and may limit patient access to medications by complicating insurance coverage and reimbursement at the pharmacy. It is also a supply-and-demand issue. Canada's market is approximately one-tenth the size of the United States' and was never designed to serve as a supply source for other countries. Any importation framework should also fully consider the impact on medication availability in Canada and the potential consequences for patient care in both Canada and the U.S.

Thank you for the opportunity to submit comments on this notice. If you have any questions or would like to meet with APhA and our nation's pharmacists to discuss the integrity of the U.S. prescription drug supply chain, please contact Corey Whetzel, APhA's Senior Manager, Regulatory Affairs, at cwhetzel@aphanet.org.

Sincerely,



Michael Baxter
Vice President, Government Affairs

[13] *See* Aaron Kearsley, *Section 804 Importation Program: Projecting Cost Savings for the American Consumer*, HHS (Mar. 3, 2026). Available at: https://www.fda.gov/media/191430/download?attachment. *See also* Carole Ramos-Izquierdo, *Section 804 Importation (SIP) Informal Meetings*, FDA (Mar. 3, 2026). Available at: https://www.fda.gov/media/191429/download?attachment.