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FDA Greenlights Florida's Proposal for Importing Prescription Drugs From Canada

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On Friday, January 5, 2024, the US Food and Drug Administration (FDA) authorized the Section 804 Importation Program (SIP) proposal of Florida's Agency for Health Care Administration (FAHCA).[1] The SIP is a pathway that allows importation of certain prescription drugs from Canada, if FDA determines that the importation poses no additional risk to public health and safety and achieves significant reduction in the cost of covered products for American consumers.[2] While Florida is the first state to receive authorization for importation under Section 804, its recent authorization may lead to renewed activity in this area from other states, as well as the pharmaceutical industry, but many questions remain unanswered.

Background on the SIP

In 2000, Congress added Section 804 to the Federal Food, Drug, and Cosmetic Act (FDCA), directing the Department of Health and Human Services (HHS) to promulgate regulations permitting pharmacists and wholesalers to import prescription drugs into the US from certain industrialized countries. Section 804 was later amended by Congress in 2003 to limit the country of origin to Canada.

On October 1, 2020, FDA issued a final rule implementing the Section 804 provisions, and the following month, on November 23, 2020, the FAHCA filed its SIP proposal. In August 2022, Florida and the FAHCA filed suit against FDA and HHS, alleging that FDA had unlawfully withheld and unreasonably delayed a decision on the proposal. FDA indicated an expectation to issue a decision on the Florida SIP proposal by October 2023;[3] however, additional questions regarding the anticipated reduction in cost to the public and the location of the warehouse for imported products necessitated an amended proposal from the FAHCA, which in turn pushed FDA's decision to January of this year.

SIP approval does not mean immediate importation of all prescription drugs from Canada

While FDA's authorization allows the FAHCA to operate its importation program for an initial two-year period, it does not give Florida carte blanche to import Canadian drugs over FDA-approved products, as Section 804 and its implementing regulations – not to mention Canadian law – limit the drugs that are eligible for importation.

To be eligible for importation, drugs must be approved by Health Canada and must meet the conditions for FDA approval apart from FDA-approved labeling. Certain categories of drugs – including biologics, controlled substances and drugs subject to a Risk Evaluation and Mitigation Strategy (REMS) in the US are ineligible for importation through a SIP.[4] Drugs that cannot be repackaged without breaching the container closure system also are ineligible for importation.[5]

Section 804 and its implementing regulations also place additional requirements on individual shipments of eligible drugs, which may slow the flow of medication from Canada to Floridians. The FAHCA must submit – and FDA must grant – a Pre-Import Request for **each** drug shipment.[6] Following entry into the US, eligible prescription drugs also are subject to examination. Although the importer is required to submit a Pre-Import Request at least 30 days prior to the scheduled arrival of a drug shipment, FDA's

authorization letter indicates that both review of the Pre-Import Request and subsequent examination of the shipment may each take longer than 30 calendar days. The manufacturer or importer also must conduct testing of the prescription drugs to ensure compliance with specifications and standards,[7] and the drugs must be relabeled to conform to the labeling of the applicable FDA-approved product, with the exception of the national drug code (NDC), lot number, name of importer, and a disclaimer that the drugs were imported from Canada under a SIP and without the authorization of the applicable US New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) holder. [8]

Finally, Canadian regulations preclude shipment of drugs outside of Canada if the shipments would cause or worsen a shortage of that drug within Canada. In a January 8 press release, Health Canada stated that it has reminded regulated parties of this obligation, and that it will take immediate action to address any noncompliance in order to safeguard Canada's drug supply. Bulk importation from Canada into the US is likely to be met with high scrutiny from Health Canada, which, in turn, may deter Canadian manufacturers and wholesalers from shipping products to Florida.

Looking ahead

Currently, sponsorship of a SIP proposal may only be submitted by states and tribes within the US. Based on publicly available information, at least five other states have submitted SIP proposals to FDA. New Hampshire's proposal was denied by FDA in November 2022, while the proposals of Colorado, Maine, New Mexico and Vermont are still pending.[9] North Dakota introduced a bill, and Texas enacted a law, allowing for a state drug importation program,[10] but they have not publicly stated whether they have submitted a SIP proposal to FDA, nor have they issued any public comment on FDA's approval of the Florida SIP.[11] FDA's long-awaited decision may spur further activity from these or other states.

The Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO) have voiced vehement opposition to importation under Section 804 due to safety concerns and have indicated that they "are exploring all options" in response to FDA's announcement. PhRMA previously filed suit against HHS for alleged violations of the Administrative Procedures Act and the First Amendment; however, the case was dismissed for lack of standing at the time, as there was no certainty that a SIP would be authorized and no indication of which drugs would be granted importation. With Florida's authorization in hand, plaintiffs should be able to overcome such justiciability challenges.

The FAHCA has indicated that it intends to begin by importing "a small number of drug classes" targeting chronic health conditions – such as HIV/AIDS, mental illness, prostate cancer and urea cycle disorder – for individuals under the care of Florida's Agency for Persons with Disabilities, Department of Children and Families, Department of Corrections and Department of Health. The agency intends to later expand the program to include Medicaid participants.

Cooley's life sciences and healthcare regulatory practice is continuing to monitor developments in this area. Please do not hesitate to reach out to a member of your Cooley team if you have questions about the SIP process or implications of FDA's recent actions.

*Cooley senior regulatory analyst **Kelly Marco** also contributed to this alert.*

Notes

1. There is a separate pathway for importation of unapproved drugs under section 801 of the FDCA. Under this "multi-market approved product" (MMA) pathway, drugs manufactured and authorized for sale outside of the US may obtain marketing approval if the manufacturer has authorized and labeled the drug for marketing in the US and has labeled it for marketing in the US. See 21 USC 381.

2. 21 USC §384(l) – Requiring the HHS to certify to Congress that implementation of the importation program poses no additional risk to public health and safety and will result in significant cost reduction for the covered products.
3. Defs.' second suppl. status report for APA claim, *State of Florida, et al., v. Food and Drug Admin., et al*., No. 8:22-cv-01981-TPB-JSS, M.D. Fla.
4. 21 CFR §251.2.
5. 21 CFR §251.13(c).
6. 21 CFR §251.5.
7. 21 CFR §251.16.
8. 21 CFR §251.13(4).
9. See, e.g., Texas Health and Human Services, **Wholesale Prescription Drug Importation Program Report**, December 1, 2023, providing a summary of progress on SIP proposals in Colorado, Florida, Maine, New Hampshire, New Mexico and Vermont.
10. S. Bill 2212, 67th Leg. (N.D. 2021-23); Tex. Health & Safety Code §444.002.
11. SIP proposals are not required to be made public, but states may choose to disclose them. State-specific information provided is based upon what the states have made publicly available.

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