# Health Industry Alert

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## Trump Administration Issues Proposed Policies to Facilitate Importation of Prescription Drugs from Canada, Other Countries

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### Key Points

- FDA issues a Proposed Rule to allow states and other entities to import certain prescription drugs from Canada.
- In addition, FDA issues draft guidance for industry to explain how drug manufacturers can import their own products intended for marketing in a foreign country.
- It will be many months before either proposal is finalized and, even then, there are serious questions about the feasibility of implementing these policies.
- Limited cooperation from Canada and drug manufacturers could hamper the ability of these programs to import drugs.

**Background**

*Proposed Rule on Importation from Canada*

On Wednesday, December 18, 2019, the U.S. Food and Drug Administration (FDA) issued a notice of proposed rulemaking that would allow for the importation of certain prescription drugs from Canada.[1] Public comments on the proposed rule are due on March 6, 2020.

As proposed, a state, tribal or territorial government can establish a time-limited "Section 804 Importation Program" (SIP) for the purpose of importing prescription drugs from Canada.[2] These programs would need to be individually authorized by FDA and managed by the state or non-federal governmental sponsor that formed the SIP.[3] The SIP proposal must identify a foreign seller licensed with Health Canada as well as an importer, a licensed wholesaler or pharmacist. Importers or manufacturers would be responsible for testing to establish the drugs' authenticity and degradation.[4] Once test results are approved by FDA, the drug products would need to be re-labeled to comply with all labeling requirements under the Federal Food, Drug, and Cosmetic Act (FDCA).[5] Importers would be required to report safety information, including adverse


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events, to FDA, and the SIP sponsors would be responsible for carrying out any product recalls.[6]

Biologics, controlled substances, intravenously injected or infused drugs, and drugs inhaled during surgery are statutorily ineligible for importation under section 804 of the FDCA.[7] Other drug products lawfully sold in Canada and the U.S. would be eligible for importation, though FDA proposes to also exclude drugs subject to risk evaluation and mitigation strategies (REMS), as well as those injected intrathecally or intraocularly.[8] The agency would make "product-by-product" determinations regarding eligibility of certain categories of drugs, including drug-device combination products as well as all sterile drugs.

*Draft Guidance on Manufacturer Importation from Any Foreign Country*

Also on December 18, FDA issued draft guidance for industry, "Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the FDCA." The draft guidance describes procedures by which drug manufacturers could import prescription drugs and biologics that are intended for sale in any foreign country provided they also have FDA approval. FDA will consider comments on the draft guidance received by February 21, 2020.

The guidance seeks to facilitate drug manufacturers importing for sale in the U.S. multi-market approved (MMA) products, which are essentially any FDA-approved prescription drugs or biologics manufactured abroad and lawfully marketed in another country. The draft guidance makes clear that imported MMA products would also be obligated to meet pedigree and product tracing requirements under the Drug Supply Chain Security Act (DSCSA).[9] MMA products would be required to satisfy other regulatory provisions applicable to FDA-approved drugs, such as those relating to misbranding, adulteration, adverse event reporting, recalls and Risk Evaluation and Mitigation Strategies (REMS), among others.[10]

Most importantly, the draft guidance explains how manufacturers may establish unique national drug codes (NDCs) for imported MMA products—with changes to either the labeler or product code—such that the manufacturer might circumvent contractual obligations with trading partners in order to offer these products at a lower price.[11] There would be certain conforming requirements for submitting a supplement to the drug or biologic's approval and approved labeling as well.[12]

**Analysis & Outlook**

*Political Context*

The release of these proposals follows months of statements by President Trump and longstanding speculation about executive action to grant Americans access to lower-price prescription drugs abroad. The President had also made multiple visits to Florida to tout Gov. Ron DeSantis' (R-FL) plan to import prescription drugs from Canada, which requires federal approval.

The Democratic-controlled House passed a sweeping bill that aims to reduce spending on drugs by billions of dollars. Congressional Republicans also have drug pricing proposals. President Trump and some in Congress have supported a Canadian drug importation proposal, though much of the pharmaceutical industry and some drug safety advocates have opposed Canadian importation plans in the past.

With the White House's signature plan to launch a new payment model tying drug prices to an international pricing index in a holding pattern, and other significant policies blocked by courts, the President has been looking to score a win on drug pricing.

*The Timeline*

Given the historical pace of FDA rulemaking, and the particular challenges with operationalizing this proposal, it would be ambitious to publish a final rule much before the 2020 election, and it is unlikely that any Americans will have access to imported drugs by then.

Following publication in the *Federal Register* on December 23, 2019, there are 75 days for public comment. FDA will need to consider, and respond to, these comments when fashioning a final rule. Even assuming FDA does so at near-record pace of six to nine months, the program would take several additional months to implement.

*Implementation Hurdles*

Neither proposal is without complicating factors and, for various reasons, it is unlikely that there will be large-scale participation.

Several proposed requirements such as the requirement that importers perform testing against manufacturer data require cooperation from the drug manufacturer. If collaborating would lead to substantial price pressures in the domestic product, manufacturers may resist sharing information with the importer. Moreover, drug manufacturers could add clauses to their contracts that restrict the ability of purchasers in Canada to participate in an SIP or otherwise sell the drugs outside of Canada.

In addition, Canadian regulators have multiple levers to curtail the program. Canada's population is less than 38 million people, roughly one-tenth of the U.S. population. Any large-scale importation program could cause shortages and supply disruptions in Canada. Health Canada, the federal department responsible for pharmaceutical regulation, has stated that it would "take action to ensure that Canadians have uninterrupted access to the prescription drugs they need."[13] Health Canada, or Canadian lawmakers, could prohibit or limit participation in the program.

Lastly, there is considerable complexity and uncertainty for participants, even beyond the contours of the proposed rule. The program requires importers to oversee adverse event reporting and SIP sponsors to be responsible for product recalls. These processes require technical knowhow and can be costly, particularly if the volume is substantial. There could also be tort liability and other regulatory pitfalls for participants, all of which translates into potentially significant costs.

[1] FDA, Proposed Rule; Importation of Prescription Drugs, 4164-01-P (Dec. 18, 2019), available at https://www.federalregister.gov/documents/2019/12/23/2019-27474/importation-of-prescription-drugs [hereinafter "Proposed Rule"; all citations to the display copy].

[2] *Id*. at 22.

[3] *Id*. at 6.

[4] *Id*. at 27.

[5] *See id*. at 55, 88-92.

[6] *Id*. at 28.

[7] 21 U.S.C. § 384(a)(3).

[8] Proposed Rule, at 32-33.

[9] FDA, Importation of Certain Food and Drug Administration-Approved Human Prescription Drugs, Including Biological Products under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry, at 10-11 (Dec. 2019), available at https://www.hhs.gov/sites/default/files/importation-of-certain-fda-approved-human-presciption-drugs-including-biological-products.pdf [hereinafter "Draft Guidance"].

[10] *Id*. at 13.

[11] *Id*. at 9.

[12] *See id*. at 6-9.

[13] Allison Martell, Canada warns U.S. against drug import plans, citing shortage concerns, Reuters Health News, Jul. 18, 2019, available at https://www.reuters.com/article/us-canada-pharmaceuticals-exports-exclus/exclusive-canada-warns-u-s-against-drug-import-plans-citing-shortage-concerns-idUSKCN1UD2LN.