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Vizient Office of Public Policy and Government Relations

Regulatory Update: FDA Proposed Rule – Importation of Prescription Drugs (Docket No. FDA-2019-N-5711)

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Summary

On December 23, 2019, the Food and Drug Administration (FDA) issued a Proposed Rule which provides a framework to allow importation of certain prescription drugs from Canada. As proposed, Section 804 Importation Program (SIP) Sponsors (e.g., states or certain other non-federal governmental entities) and SIP co-sponsors (e.g., pharmacists, wholesalers) would be able to submit time-limited SIP Proposals to FDA to authorize a proposed prescription drug importation plan.

Comments on the Proposed Rule are due on March 3, 2020.

Background

Alongside the Proposed Rule, the FDA also released Draft Guidance, which outlines a separate pathway allowing drug manufacturers to obtain an additional National Drug Code for an imported FDA-approved drug that was also authorized for sale in a foreign country. This summary, however, focuses on the Proposed Rule which provides regulations for commercial importation, consistent with Section 804 of the Federal Food, Drug & Cosmetic (FD&C) Act, as amended in 2003.

As passed in 2003, Section 804 of the FD&C Act permits U.S. pharmacists or wholesalers to import a limited scope of Canadian prescription drugs (in accordance with regulations), if the Secretary of the Department of Health and Human Services (HHS) certifies that importation will "pose no additional risk to the public's health and safety" and that it will "result in a significant reduction in the cost of covered products to the American consumer." To date no Secretary has provided this certification. In this Proposed Rule, the FDA indicates the Secretary will provide certification to Congress in coordination with FDA's release of the final rule.

Key Definitions

Foreign Seller means an establishment within Canada engaged in the distribution of an eligible prescription drug that is imported or offered for importation into the United States. A Foreign Seller must have an active drug establishment license as a drug wholesaler by Health Canada's Health Products and Food Branch (HPFB or Health Canada). A Foreign Seller must be registered with provincial pharmacy regulatory authorities to distribute HPFB-approved drugs. A Foreign Seller must also be registered with FDA under section 804 of the Federal Food Drug and Cosmetic Act in accordance with the requirements described in this part.

Importer must be a State-licensed pharmacist, or a State or FDA-licensed wholesaler, and is the U.S. owner of an eligible prescription drug at the time of entry into the United States. An Importer's pharmacist or wholesaler license must be in effect (*i.e.,* not expired) and the Importer must be in good standing with the licensor.

Section 804 Importation Program ("SIP") is a program under section 804 of the Federal Food, Drug, and Cosmetic Act that has been authorized by FDA for the importation of eligible prescription drugs from Canada.

Section 804 Importation Program Sponsor ("SIP Sponsor") means a State, tribal, or territorial governmental entity that regulates wholesale drug distribution and/or the practice of pharmacy, and a co-sponsor or co-sponsors, if any, that submits a proposal to FDA that describes a program to facilitate the importation of prescription drugs from Canada under section 804 of the Federal Food, Drug, and Cosmetic Act. A co-sponsor must be a State, tribal, or territorial governmental entity, a pharmacist, or a wholesaler.

- While FDA proposes that every SIP be sponsored by a State, tribal, or territorial governmental entity (as defined above), the agency seeks comment on whether it could be possible, without posing additional public health risk, for a pharmacist or wholesaler to be a SIP Sponsor without a State, tribal or territorial government co-sponsor.
- FDA specifically requests comment on whether other types of non-governmental entities, such as group purchasing organizations, pharmacy benefit management or union health and welfare plans, should be permitted to co-sponsor SIPs.
- FDA also seeks feedback on whether it is appropriate for a co-sponsor to also serve as an Importer. If so, what safeguards are needed to ensure there is adequate oversight of a co-sponsor that also acts as the Importer?

Costs and Benefits

In the Proposed Rule, FDA indicates it lacks information about the expected scale, scope, number and type of importation programs to determine costs and benefits for consumers, the Federal government, SIP Sponsors, and Importers, among other stakeholders. In addition to costs associated with developing and implementing an importation plan, SIP Sponsors must also demonstrate cost savings to FDA. Cost savings may be shown by comparing acquisition costs or retail prices with the prices per unit of the drug that aims to be imported. FDA seeks comment on relevant measures that may be used to demonstrate cost-savings and how to ensure there is a significant reduction in costs to the American consumer.

Process

The Proposed Rule outlines several steps that must occur before prescription drugs from Canada can be imported. The importation process includes an SIP Proposal, Pre-Import Request, importation and post-importation requirements, as described below.

SIP Proposal. An SIP Sponsor (e.g., State, tribal, or territorial governmental entity), likely working with a pharmacist or wholesale distributor as a co-sponsor, starts the approval process by developing an SIP Proposal for the FDA to review and authorize The Proposed Rule provides an extensive list of information, assurances, processes (e.g., recall plan) and records that must be included in the SIP Proposal, as outlined on pages 70829-70830 of the Proposed Rule.

For example, the SIP Proposal must include information for key contacts (e.g., Importer, Foreign Seller, FDA-registered repackager or relabeler) and a list of all past disciplinary actions imposed against the Foreign Seller or the Importer by State Federal or Canadian regulatory bodies, Foreign Seller's Health Canada inspectional history and the Importer's State and Federal inspection history. In addition, the SIP Proposal should clarify details of the importation plan, such as how the Sponsor will ensure the eligible prescription drug meets laboratory testing requirements; supply chain security; proper labeling; SIP participants' compliance; proper storage, handling and distribution practices; and satisfaction of post-importation reporting requirements. In addition, the SIP Proposal should demonstrate how it would reduce costs for American consumers.

The Proposed Rule specifically states that SIP Sponsors will be responsible for ensuring that all SIP participants comply with relevant FDA law and regulations. FDA seeks specific feedback regarding what elements should be included in a compliance plan, such as a description of the division of responsibilities between co-sponsors. In addition, FDA requests comments on what the division of responsibilities between co-sponsors should be and whether there are certain arrangements that should not be permitted

(e.g., can a pharmacist or wholesaler be both a SIP co-sponsor and an Importer within the same SIP). Once FDA authorizes a SIP Proposal, the SIP's Importer needs FDA's permission to start importation.

Pre-Import Request. To receive FDA's permission to start importation, the Importer (e.g., pharmacist, wholesale distributor) must submit a Pre-Import Request to FDA at least 30 days prior to the date of entry. The Pre-Import Request should address the plan for conducting the required testing and an attestation from the manufacturer that, other than Health Canada's approved labeling, the Health Canada-approved drug meets the conditions in the FDA-approved drug's application. Once the Pre-Import request is granted, the Importer may start the process for importation.

Importation. The Proposed Rule outlines two pathways by which drugs may be imported: (1) Admission to a Foreign Trade Zone with later entry for consumption and filing in the Automated Commercial Environment (ACE) when FDA-compliant; or (2) filing an entry for consumption in ACE with a request to bring the eligible prescription drugs into compliance. In addition, the Importer would need to coordinate with FDA for their review and acceptance of the required testing results. Once the requirements described in the SIP (e.g., testing, labeling) are complete, but before the products are distributed, the Importer must provide a certification to FDA. If FDA is satisfied with the certification and/or inspection or sampling, FDA will issue a Notice of Release which allows the prescription drugs to be admitted into the United States.

Post-Importation Requirements. Once a drug is relabeled and enters the U.S. supply chain, there are several post-importation requirements for the SIP Sponsor and Importer. The SIP Sponsor would be responsible for reporting cost-savings to FDA and effectuating a recall, if warranted. The SIP Sponsors must also submit quarterly reports to FDA. The Importer's post-importation responsibilities would include adverse event reporting and investigation, field alert reports, certain individual case safety reports (ISCRs), recalls, and record retention. More information on post-importation requirements can be found on pages 70837-70839 of the Proposed Rule.

Drugs Eligible for Import

The Proposed Rule defines "eligible prescription drug" and requires each SIP Sponsor to specify which products it intends to import. Drugs eligible for import are those that are approved by Health Canada and meet conditions required by an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA) (except for the product displaying Canadian labeling).

Under the Proposed Rule, the following types of drugs are not eligible for importation: controlled substances, biological products (including insulins), infused drugs, intravenously injected drugs, inhaled drugs, and drugs subject to a Risk Evaluation and Mitigation Strategy (REMS), among others. FDA seeks feedback on whether other categories of products (e.g., inhaled drugs, drug-device combination products, modified-release drugs, sterile drugs, ophthalmic drugs, drugs with boxed warnings, drugs requiring special storage conditions) should be eligible for import.

Supply Chain Requirements

American manufacturers, wholesale distributors, repackagers and pharmacies are currently implementing the Drug Supply Chain Security Act (DSCSA) which outlines the steps to build an electronic, interoperable system to trace prescription drugs as they are distributed in the United States. However, imported drugs and foreign trading partners are not included in the closed supply chain DSCSA establishes.

To address DSCSA challenges associated with drug importation, FDA proposes that the Foreign Seller or Importer would assume certain supply chain security obligations (e.g., assignment of an SSI[1], maintaining records related to serialization, adherence to good manufacturing practices, verifying a drug is not suspect or illegitimate, responding to verification requests, relabeling) and exempts certain importation-related transactions from DSCSA's requirements. The Proposed Rule makes clear the imported drug's National Drug Code (NDC) will differ from its FDA-approved counterpart. FDA also proposes to require manufacturers to provide information about the imported drug's movements before it reached the U.S. supply chain. The Importer would need to ensure that the drug complies with all U.S. labeling requirements related to adulteration, labeling and misbranding. Given the Importer's proposed responsibilities, FDA request comments on whether additional standards or requirements are needed for Importers.

What's Next?

Comments are due by March 3, 2020. FDA will review comments before finalizing the Proposed Rule. The Final Rule would be effective 30 days after it is released. Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this Proposed Rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern.

Additional Resources

Please reach out to Jenna Stern, Sr. Regulatory Affairs and Public Policy Director in Vizient's Washington, D.C. office if you have any questions or if Vizient can provide any assistance as you consider these issues. She may be reached at (202) 354-2673 or jenna.stern@vizientinc.com.

[1] *Section 804 Serial Identifier ("SSI")* means a unique alphanumeric serial number of up to 20 characters that is assigned and affixed by the Foreign Seller to each package and homogenous case of the product that it intends to sell to the Importer. For purposes of the SSI, "package" means the smallest individual saleable unit of product for distribution that is intended by the Foreign Seller for sale to the Importer located in the United States, and "individual saleable unit" means the smallest container of product sold by the Foreign Seller to the Importer.