Importation of Prescription Drugs Final Rule Questions and Answers

Guidance for Industry

(Small Entity Compliance Guide)

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Regulatory Affairs (ORA)

May 2022
Import

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TABLE OF CONTENTS

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I. INTRODUCTION

This guidance is intended to help small entities better understand the final rule, "Importation of Prescription Drugs," published October 1, 2020 (85 FR 62094). The Secretary of Health and Human Services issued the final rule to implement section 804(b) through (h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384(b) through (h)) to allow importation of certain prescription drugs from Canada.[2] The purpose of the final rule is to achieve a significant reduction in the cost of covered products to the American consumer while posing no additional risk to the public's health and safety.

The final rule became effective November 30, 2020. FDA has prepared this guidance in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121, as amended by Public Law 110-28). This guidance document restates in plain language the legal requirements set forth in the final rule and is intended to assist small entities in complying with the final rule.[3]

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by the Center for Drug Evaluation and Research and the Office of Regulatory Affairs at the Food and Drug Administration with assistance from the Office of Combination Products.
[2] In addition to drugs, drug-device combination products (see 21 CFR 3.2(e)) may be eligible for importation under the rule. The answers provided in this guidance are also applicable to those combination products.
[3] See 21 CFR part 251.

II. DISCUSSION

Q1. Who may submit an importation program proposal? Who may import eligible prescription drugs?

Under the final rule, section 804 of the FD&C Act will be implemented through time-limited Section 804 Importation Programs (SIPs), which will be reviewed and authorized by FDA and managed by States or Indian Tribes, or in certain future circumstances by pharmacists or wholesale distributors (SIP Sponsors). A SIP may be co-sponsored by a State, Indian Tribe, pharmacist, or wholesale distributor. The personal importation provisions in section 804(j) of the FD&C Act will not be implemented through the final rule.

In an authorized SIP, an Importer, which may be a pharmacist or a wholesaler, will import eligible prescription drugs. An Importer must be a licensed pharmacist or wholesale distributor and the Importer must be the U.S. owner of an eligible prescription drug at the time of entry into the United States. The Importer's pharmacist license or wholesale distributor license (if issued by a State and not FDA) must be issued by a State that is a SIP Sponsor or SIP Co-Sponsor. An Importer's pharmacist or wholesale distributor license must be in effect or active (that is, not expired) and the Importer's license must be in good standing with the licensor.

Q2. What prescription drugs are eligible for importation under the final rule?

The final rule requires that a SIP Sponsor specify the eligible prescription drugs that will be included in the SIP. To be eligible under the final rule, a drug must be approved by the Health Canada's Health Products and Food Branch (HPFB) and it must have HPFB-approved labeling when marketed in Canada. Except for not having the required U.S. labeling when marketed in Canada, an eligible prescription drug must otherwise meet the conditions in an FDA-approved new drug application or abbreviated new drug application. Essentially, eligible prescription drugs are those that could be sold legally on either the Canadian market or the American market with appropriate labeling.

The final rule excludes certain types of drug products from eligibility: controlled substances, biological products, infused drugs (including peritoneal dialysis solutions), drugs that are inhaled during surgery, drugs that are injected intravenously (into a vein), intrathecally (into the spinal fluid), or intraocularly (into the eye), drugs that are subject to a risk evaluation and mitigation strategy (REMS), and drugs that are not subject to certain provisions of the Drug Supply Chain Security Act. For a drug product not excluded by the final rule, FDA will determine whether the product can be imported safely in the context of a specific SIP Proposal on a product-by-product basis. A SIP Sponsor would need to explain in its SIP Proposal how it will address any concerns arising from the manufacture, storage, and transport of each eligible prescription drug, including concerns related to controlling contamination, preserving sterility, and ensuring stability.

Q3. Does the final rule provide for importation of drugs from countries other than Canada?

The final rule only relates to importation from Canada because it will implement the statutory authority under section 804(b) of the FD&C Act, and section 804(b) is limited to importation of prescription drugs from Canada.

Q4. How can SIPs obtain eligible prescription drugs?

In an authorized SIP, a Foreign Seller in Canada will purchase an eligible prescription drug directly from the drug's manufacturer and the Importer in the United States will buy the drug directly from the Foreign Seller. Each drug's supply chain under a SIP must be limited to three entities, i.e., one manufacturer, one Foreign Seller, and one Importer.

The final rule requires that the Foreign Seller be licensed to wholesale drugs by Health Canada and registered with FDA as a Foreign Seller. The Foreign Seller cannot have an international pharmacy license that allows it to distribute drugs that are approved by countries other than Canada and that are not HPFB-approved for distribution in Canada.

The final rule also includes a number of supply chain requirements for Foreign Sellers. FDA retains the authority not to authorize a SIP or to discontinue a SIP, if a Foreign Seller does not meet all the relevant requirements.

Q5. Can a SIP Proposal be submitted without identification of a Foreign Seller?

Yes, FDA may use a phased review process to review a SIP Proposal that does not identify a Foreign Seller in an initial submission but the SIP cannot be authorized by FDA without an identified Foreign Seller. Under section 251.4 of the final rule, there is the possibility that a SIP Proposal would not be authorized if a Foreign Seller is not identified within 6 months of the initial submission date of the SIP Proposal.

Q6. What are the importation requirements under the final rule?

After FDA has authorized a SIP Proposal, the Importer must submit a Pre-Import Request to FDA at least 30 calendar days before the scheduled date of arrival or entry for consumption of a shipment containing an eligible prescription drug covered by the SIP, whichever is earlier. Importation of drugs under this program cannot occur until the Importer receives formal notification from FDA that its Pre-Import Request has been granted. Entry and arrival of a shipment containing an eligible prescription drug is limited under the final rule to the U.S. Customs and Border Protection (CBP) port of entry authorized by FDA. The Importer or its authorized customs broker is required to electronically file an entry for consumption in the Automated Commercial Environment or other electronic data interchange system authorized by CBP for each eligible prescription drug imported or offered for import into the United States. These entries must be filed as formal entries. If a drug that is imported or offered for import does not comply with the final rule, the drug may be subject to refusal under the FD&C Act.

Q7. How are eligible prescription drugs tested?

Section 804 of the FD&C Act and the final rule contain a number of provisions that work together to help ensure the quality of products imported under this rule. Among other things, in accordance with section 804 of the FD&C Act, the final rule requires the manufacturer or the Importer to conduct testing of eligible prescription drugs for authenticity, for degradation, and to ensure that the eligible prescription drugs are in compliance with established specifications and standards (Statutory Testing). The final rule provides that unless the manufacturer conducts the required testing, the Importer must submit a Statutory Testing plan that includes a description of how samples will be selected, the name and location of the qualifying laboratory in the United States that will conduct the Statutory Testing, and a description of the testing method or methods that will be used to conduct the Statutory Testing. The final rule requires that the manufacturer provide the Importer with, among other things, protocols to support the required testing, including a validated stability-indicating assay so the drug can be tested for degradation. The results of this testing will be subject to review and acceptance by FDA.

Q8. What are the labeling requirements for eligible prescription drugs?

Eligible prescription drugs must be relabeled with the required U.S. labeling, including patient labeling such as Medication Guides, Instruction for Use documents, and patient package inserts. However, as described in the final rule, the Importer's National Drug Code (NDC) for the eligible prescription drug must replace any other NDC otherwise appearing on the label of the FDA-approved drug and the labeling must include, among other things, the lot number assigned by the manufacturer, the name and place of business of the Importer, and the statement: "[This drug was/These drugs were] imported from Canada without the authorization of [Name of Applicant] under the [Name of SIP Sponsor] Section 804 Importation Program."

Q9. What needs to be done after importation of eligible prescription drugs?

Consistent with the FD&C Act, the final rule includes post-importation requirements. Each SIP Sponsor is required to provide FDA with data and information about its SIP, including the SIP's cost savings to the American consumer. An Importer is required to submit adverse event, field alert, and other reports to a drug's manufacturer and to FDA. If FDA or any participant in a SIP determines that a recall is warranted, the SIP Sponsor is responsible for effectuating the recall. The final rule requires that each SIP proposal contain a written recall plan that describes the procedures to perform a recall of the product and specifies who will be responsible for performing those procedures. SIP Sponsors and other SIP participants must also agree to submit to audits of their books and records and inspections of their facilities as a condition of participation in a SIP.

Q10. Can eligible prescription drugs imported under a SIP be returned?

Yes, however, the SIP Sponsor must ensure that a product that is returned after distribution in the United States is properly dispositioned in the United States in accordance with SIP's return plan as required in the final rule, if it is a non-saleable return, in order to protect patients from expired or unsafe drugs. The SIP Sponsor must prevent returned eligible prescription drugs from being

exported from the United States. In certain circumstances, a saleable, returned eligible prescription drug may be re-distributed in the United States in accordance with the requirements in the final rule.

Q11. For how long are SIPs authorized? Can a SIP's authorization be extended?

A SIP may be authorized for up to 2 years from the date of importation of its first shipment. FDA may extend the authorization period for up to 2 years at a time.

Q12. Can a Sponsor make changes to its SIP?

Yes, a SIP Sponsor may propose to modify an authorized SIP. In reviewing a proposal to modify a SIP, among other things, FDA may take into account information learned subsequent to authorization of the SIP. A Sponsor must not make or permit any changes to a SIP without FDA's authorization.