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HHS and FDA Release Proposed Rule and Draft Guidance on Importation of Drugs Originally Intended for Foreign Markets

December 19, 2019

Food, Drugs, and Devices

On December 18, 2019, the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) issued a notice of proposed rulemaking on "Importation of Prescription Drugs" (the "NPRM") and a Draft Guidance titled "Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act" (the "Draft Guidance"). The NPRM and the Draft Guidance, if finalized, would create two pathways for importation of certain drugs originally intended for foreign markets. The NPRM and Draft Guidance reflect two pathways initially proposed in HHS's Safe Importation Action Plan (the "SIAP"), released on July 31, 2019.

Comments to the NPRM are due 75 days from publication in the Federal Register. Comments to the Draft Guidance are due 60 days from publication of the notice in the Federal Register.

Summary of the NPRM on Importation of Prescription Drugs

Section 804 of the Federal Food, Drug, and Cosmetic Act ("FDCA") allows HHS to promulgate regulations that would allow pharmacies and wholesalers to import certain FDA-approved prescription drug products from Canada. Congress conditioned the implementation of Section 804 on an initial certification by the HHS Secretary. If effectuated, section 804(b)-(h) allows HHS to establish a commercial importation program of drugs from Canada, and section 804(j) allows personal importation of certain prescription drugs. Section 804(l) provides that the section shall become effective only if the HHS Secretary is able to certify that implementing the section (1) will pose no additional risk to public health and safety, and (2) will result in a significant reduction in the cost of drugs to the American consumer.

The NPRM, if finalized, would implement section 804(b)-(h) of the FDCA, the commercial importation provisions of section 804. The proposed rule, if finalized, would not implement the personal importation provisions under section 804(j) of the FDCA. The NPRM states that HHS intends to provide a certification under section 804(l) at the same time that it issues a final rule. Certification would be conditioned on the final rule becoming effective with all the requirements included when finalized. The NPRM states that the rule is not severable; if one or more provisions become invalid, certification would become null and void.

HHS, through FDA, would implement section 804 through time-limited Section 804 Importation Programs (SIP). Each SIP which would be authorized by FDA in 2-year increments and managed by SIP sponsors, which would be a State, tribal, or territorial governmental entity. A

non-federal governmental entity and any co-sponsors would submit a SIP Proposal to FDA explaining how the SIP would pose no additional risk to the public's health and safety and would "result in a significant reduction in the cost to the American consumer" of the drugs that the Sponsor seeks to import. The SIP Proposal must specify the foreign seller (Canadian establishment distributing eligible prescription drugs and purchasing drugs directly from the manufacturer) and the importer (licensed wholesale drug distributor or pharmacist that owns the eligible prescription drug) involved in the program. FDA would decide whether to authorize a SIP Proposal.

Eligible Prescription Drugs

Each sponsor would specify the "eligible prescription drugs" to be included in the SIP for importation from Canada. An eligible prescription drug must be approved by Health Canada's Health Products and Food Branch (HPFD) and but for the fact it bears Canadian labeling, otherwise meet the conditions in a FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA). Further, an eligible prescription drug cannot be a controlled substance, biological product (as defined in section 351 of the Public Health Service Act), infused drug, intravenously injected drug, or a drug that is inhaled during surgery. FDA proposes to also exclude two categories of parenteral drugs (intrathecally injected drugs and intraocularly injected drugs) as well as drugs subject to risk evaluation and mitigation strategies (REMS).

Importation Process

If FDA authorizes a SIP proposal, the NPRM outlines the process for how an Importer in a SIP can import eligible prescription drugs.

- Pre-Import Request: If FDA authorizes a SIP proposal, an Importer must submit a Pre-Import Request at least 30 days prior to the date of arrival of a shipment containing a drug covered by the SIP. The Request must include a "Statutory Testing plan" which would describe how eligible prescription drugs would be selected for testing. The NPRM states that testing must either be performed by the manufacturer of the eligible prescription drug, or if the importer tests the drug, the manufacturer must supply the information the importer needs to authenticate the drug and confirm that drug labeling complies with requirements under the FDCA.
- Importation: Drugs covered under a SIP can be imported under two proposed pathways: admission to a foreign trade zone with later entry when compliant with the FDCA, or filing an entry for consumption in the electronic data exchange system with a reconditioning request to bring eligible prescription drugs into compliance with the FDCA.
- Importer's Certificate: After the Importer completes all testing, labeling, and any other requirements in the SIP, the Importer will provide a certification to FDA. At that point, FDA may conduct an inspection or sampling to determine compliance. If FDA determines that the SIP conditions have been fulfilled, FDA will issue a Notice of Release allowing the imports for admission into the United States.

FDA notes that under the proposed rule, FDA maintains discretion to revoke authorization of a SIP "at any time for any reason in FDA's discretion."

Additional Requirements for Section 804 Drugs

The NPRM proposes a number of other requirements for section 804-imported drugs. These requirements include, among others:

- Compliance with the DSCSA. The NPRM proposes to require products imported under section 804 to comply with the Drug Supply Chain Security Act (DSCSA) but exempts certain transactions from DSCSA requirements because "they would be difficult or impossible for section 804 imported drugs to meet."
- Labeling. As required by statute, a drug covered by section 804 must meet all labeling requirements of the FDCA. The NPRM also proposes that a drug imported under section 804 must bear a new National Drug Code (NDC) and be listed. The labeling must include the statement: "This drug was imported from Canada under the [Name of State or Other Governmental Entity and of Its Co-Sponsors, If Any] Section 804 Importation Program to reduce its cost to the American consumer."
- Post-Importation Requirements. Each Importer is responsible for receiving and reporting adverse events to FDA and to the manufacturer. The Importer is also responsible for submitting FDA field alert reports about the products it distributes. An SIP sponsor would be responsible for recalling products if necessary.

Summary of the Draft Guidance on Importation of Certain FDA-Approved Drugs

With two exceptions, section 801(d)(1)(B) of the FDCA states no prescription drug may be imported into the United States for "commercial use if such drug is manufactured outside the United States, unless the manufacturer has authorized the drug to be marketed in the United States and has caused the drug to be labeled to be marketed in the United States." The Draft Guidance provides a pathway for manufacturers to import their own drugs originally intended for foreign markets, consistent with section 801(d)(1)(B) of the FDCA. All human prescription drugs and biological products that are regulated drugs would be eligible for this pathway, including biologics and biosimilars.

The Draft Guidance acknowledges that the pathway is voluntary. FDA's new policy is intended to help manufacturers obtain NDCs to "address certain challenges in the private market." FDA hopes that by allowing manufacturers to obtain an additional NDC, FDA would "provide an additional avenue through which drugs could be sold at a lower cost in the U.S. market."

Multi-Market Approved Product

The Draft Guidance discusses how a manufacturer could import a "multi-market approved product" or "MMA product." FDA describes an MMA product to be an FDA-approved prescription drug that: (1) was originally manufactured outside the U.S. and authorized for marketing by another country's regulatory authority; (2) is the subject of a supplement to an NDA or a biologics license application (BLA); (3) is imported into the U.S. and authorized by the manufacturer to be imported into the U.S.; (4) continues to meet the quality standards for marketing in its originally intended market; and (5) differs from the FDA-approved drug or FDA-licensed biological product only with regard to a labeling statement.

Recommendations for MMA Products

The Draft Guidance proposes a number of recommendations before a manufacturer could introduce a MMA product into the U.S.

- Submission of a Supplement: The Draft Document recommends that an applicant seeking to market an MMA product under an NDA or BLA submit a labeling supplement to FDA. The supplement should include an "attestation" to demonstrate that the MMA product is an FDA-approved product. FDA notes that a drug offered as a MMA product without an approved supplement may be refused admission.
- New NDC: The manufacturer should propose a new NDC for the MMA product, which should include changes to either the labeler code or product code. FDA notes that to avoid confusion between different product packages with the same name, the change to the NDC "should not be solely with the package code."
- Labeling Statement: FDA recommends that the labeling of the MMA product must match FDA-approved labeling, except that the product should include a statement to differentiate the drug from other drugs that are not the subject of the guidance.

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Interested stakeholders should consider submitting written comments to the dockets for the NPRM and the Draft Guidance. The deadline for comments to the NPRM is 75 days from publication in the Federal Register. Comments to the Draft Guidance are due 60 days from publication of the notice in the Federal Register.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs, and Devices practice:

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