Food and Drug Administration Issues Historic Proposed Rule and Draft Guidance on Drug Importation

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On December 18, 2019, in a reversal of historic and substantive reservations,[1] the U.S. Food and Drug Administration (FDA or Agency) issued a notice of proposed rulemaking (Proposed Rule) that, if finalized, would allow for the importation of certain prescription drugs from Canada.[2] FDA also issued a draft guidance that offers a second pathway for the importation of drugs into the United States through manufacturer importation of drugs, including biological products, from abroad.[3]

The Proposed Rule is the first step in implementing a provision of federal law that permits the importation of certain prescription drugs from Canada under specific conditions.[4] Section 804 of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires the Secretary of Health and Human Services (HHS), after consultation with the U.S. Trade Representative and the Commissioner of Customs, to issue regulations permitting such importation. The FDA is proposing to amend and expand its regulations to implement sections 804(b) through (h), and cites to section 804 as well as its broad drug authorities in Title V of the FFDCA as the statutory basis for this rulemaking.

For section 804 of the FFDCA to become effective, the Secretary of HHS must certify that its implementation 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." FDA stated that the Secretary would make this certification to Congress upon issuance of a final rule based on this proposal.

Highlights of Proposed Rule

Under the Proposed Rule:

- FDA would review and authorize time-limited **Section 804 Importation Programs (SIPs)** managed by "States or certain other non-federal governmental entities." A SIP could be co-sponsored by a pharmacist, a wholesaler, or another state or non-federal governmental entity.
- Once approved, a SIP would manage the importation of certain prescription drugs that are approved in Canada and also meet the conditions in an FDA-approved drug application. SIPs would be authorized by FDA in **two-year increments,** with the possibility of extensions for additional two-year periods.
- Under a SIP, **the supply chain for each drug would be limited to three entities**: one manufacturer, one Foreign Seller, and one Importer. An eligible prescription drug would need to be sold by the manufacturer directly to a Canadian Foreign Seller. FDA has determined that this requirement is critical because the Agency would generally not possess information needed to trace drug products labeled for the Canadian market back to the original manufacturer. A Foreign Seller would then ship the drug directly to the Importer in the United States.
    - The pharmacist or wholesaler Importer would be broadly responsible for assuring imported drugs are not adulterated or counterfeit; each shipment of which is tested by a qualifying laboratory for authenticity and degradation; and are relabeled with FDA-approved labeling; and complies with requirements of the Drug Supply Chain Security Act (DSCSA).
    - The Foreign Seller would be required to have a wholesaler license with Health Canada, and buy eligible prescription drugs directly from the manufacturers and then sell them directly to the importer.
- Several categories of drug products would **be exempt from importation**, consistent with section 804(a)(3), including controlled substances, biological products, infused drugs, intravenously injected drugs, and drugs inhaled during surgery.FDA will also

determine whether additional drug products "can be imported safely in the context of a specific SIP Proposal on a product-by-product basis", including but not limited to dry powder inhalers, metered-dose inhalers, inhaled drugs; sterile drugs and drugs with boxed warnings or special storage conditions.

- **Eligible prescription drugs** would generally need to (1) be in compliance with labeling requirements under the FDCA, (2) include the US-approved labeling, (3) be relabeled with new information, and (4) be listed by the importer pursuant to FDA's establishment registration and listing requirements.

Notably, the DSCSA establishes the product identification, verification, and tracing requirements that manufacturers, wholesale distributors, pharmacists, and other trading partners must adhere to for covered transactions involving certain prescription drugs. Because the DSCSA did not include an exemption for drugs imported under section 804, such drugs are subject to the Act's requirements. Noting that certain DSCSA requirements may be difficult or impossible for such drugs to meet, FDA proposes to exempt from DSCSA certain transactions for drugs imported under section 804. In addition, to ensure the proposed exemptions do not compromise the security of the supply chain, this rule also proposes additional provisions over imported drugs to safeguard the public health.

The FDA is not proposing to implement the **personal drug importation** program under section 804 through this rulemaking because the Agency believes it would be too difficult to monitor drugs imported through these means.

Comments on the proposed rule are being accepted for 75 days after publication in the Federal Register.

Draft Guidance

FDA also issued a draft guidance that describes the pathway for the importation of certain drugs into the United States under section 801 of the FFDCA by the drug manufacturer as opposed to the wholesaler. The draft guidance also describes how manufacturers may secure an additional National Drug Code (NDC) for FDA-approved drugs imported under section 801, including but not limited to drugs from Canada. Such drugs could include biological products, an important difference from the Proposed Rule implementing section 804 of the FFDCA.

The eligible drug products under this guidance would be deemed "multi-market approved products" or "MMA products. To be imported into the U.S. under section 801(d)(1)(B), these products should meet the following criteria:

- Be FDA-approved under an NDA or BLA, but originally manufactured outside the United States and authorized for marketing in a foreign country;
- Have an approved NDA or BLA supplement that provides certain documentation demonstrating that the drug or biologic to be imported meets the criteria for importation have been met;
- Differ "only with regard to the labeling statement" from the FDA-approved drug;
- Will be given DSCSA-compliant product identifiers, be subject to track and trace, and comply with import entry procedures detailed in the draft guidance;

The draft guidance also recommends that the drug manufacturer include a statement on the product's label and in the prescribing information to assist pharmacists to accurately identify, dispense and bill for these products. Prescription drugs, including biological products, imported under section 801 as described in the draft guidance could be available to patients in a variety of settings, including hospitals, health care providers' offices, or licensed U.S. pharmacies, and would include the FDA-approved labeling (including prescribing information).

Comments on the draft guidance are being accepted for 60 days after publication in the Federal Register.

Conclusion

The Proposed Rule closely tracks the policies intended under section 804 and described previously in the Administration's Safe Importation Action Plan, and contemplates an importation regime carefully reviewed and overseen by the FDA. SIP sponsors and their commercial partners would be assume broad and critical responsibilities, from testing and pharmacovigilance to DSCSA compliance, that are rigorous and costly. FDA has reserved the right to exclude and exempt broad categories of drug products on a case-by-case basis that might further reduce incentives for potential SIP sponsors. Additionally, there is no assurance that SIP sponsors would be able to secure the cooperation of Health Canada or Canadian wholesalers, much less manufacturers, on whom any importation plan would rely on for critical testing and labeling requirements.

FDA notably states in the proposed rule that it is "unable to estimate the cost savings from this proposed rule, as we lack information about the likely size and scope of SIP programs and about the specific drug products that may become eligible for importation, the degree to which imported drugs would be less expensive than non-imported drugs available in the United States, and which SIP eligible products are produced by U.S. drug manufacturers." In effect, FDA acknowledges that it lacks the factual basis for the certification to Congress necessary to enable implementation of the program – that it will "result in a significant reduction in the cost of covered products to the American consumer."

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[1] Former FDA Commissioner Scott Gottlieb "Our closed drug system doesn't allow imports of unapproved foreign drugs for key historical reasons" December, 17, 2019 at https://twitter.com/ScottGottliebMD/status/1207093162470182912

[2] https://www.federalregister.gov/documents/2019/12/23/2019-27474/importation-of-prescription-drugs

[3] https://www.federalregister.gov/documents/2019/12/23/2019-27475/guidance-importation-of-certain-food-and-drug-administration-approved-human-prescription-drugs

[4] Department of Health and Human Services, "Trump Administration Takes Historic Steps to Lower U.S. Prescription Drug Prices", December 18, 2019 at https://www.hhs.gov/about/news/2019/12/18/trump-administration-takes-historic-steps-to-lower-us-prescription-drug-prices.html

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