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HHS and FDA Actions on Importation of Prescription Drugs from Canada and other Countries

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Food, Drugs, and Devices

On September 24, 2020, the Department of Health and Human Services ("HHS") and the Food and Drug Administration ("FDA") took major steps toward facilitating the importation of prescription drugs by entities other than the manufacturer, with the stated goal of lowering costs for American consumers. Pursuant to President Trump's July 24, 2020 Executive Order, HHS and FDA issued a final rule to allow for the commercial importation of certain prescription drugs from Canada without the manufacturer's authorization, and HHS issued requests for proposals ("RFPs") regarding personal importation programs and insulin reimportation programs. The FDA also released a final guidance for industry describing procedures for manufacturers seeking to import their own products originally intended for foreign markets.

The final rule is scheduled to be published in the *Federal Register* on October 1 and will become effective 60 days after publication. HHS started accepting proposals for personal importation and insulin reimportation programs the same day the RFPs issued.

I. Background

Over the past year, the Administration has taken several actions leading up to the issuance of the final rule, final guidance, and requests for proposals.

- Safe Importation Action Plan ("SIAP"): On July 31, 2019, HHS issued the SIAP outlining two pathways for importing certain prescription drugs originally intended for foreign markets. Pathway 1 would authorize demonstration projects to allow for entities other than the manufacturer to import certain prescription drugs from Canada. Pathway 2 would help facilitate manufacturers' own importation of FDA-approved drugs that they sell in other countries.
- Notice of Proposed Rulemaking ("NRPM") and Draft Guidance on Importation: On December 18, 2019, FDA implemented Pathway 1 of the SIAP by issuing an NPRM titled "Importation of Prescription Drugs" and implemented Pathway 2 of the SIAP by issuing a Draft Guidance titled "Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B)." Covington previously issued a client alert on the NPRM and Draft Guidance.
- Executive Order on Increasing Drug Importation to Lower Prices for American Patients: On July 24, 2020, President Trump signed Executive Order 13,938 to "support[] the goal of safe importation of prescription drugs." The Order instructed the HHS Secretary to

take action "as appropriate and consistent with applicable law" to (1) complete an ongoing rulemaking process to permit commercial importation of drugs from Canada; (2) facilitate grants of waivers to individuals; and (3) authorize the re-importation of insulin products upon a finding by the Secretary that it is required for emergency medical care.

II. Final Rule on Importation of Prescription Drugs

On September 24, 2020, HHS and FDA issued the final rule to implement the commercial importation provisions in subsections (b) through (h) of section 804 of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Section 804, once effective, authorizes HHS to promulgate regulations that would allow pharmacists and wholesalers in the United States to import prescription drugs from Canada without the manufacturer's authorization.

For section 804 to become effective, HHS must certify to Congress that its implementation will "pose no additional risk to the public's health and safety" and will "result in a significant reduction in the cost of covered products to the American consumer." The final rule states that HHS is making this certification with respect to section 804(b)-(h) to Congress concurrent with the issuance of the final rule.

Notably, since an earlier version of section 804 was enacted in 2000 and until now, every HHS Secretary has declined to make this certification because of the risks that section 804 would pose to public health and safety and the inability to show the required cost savings. In December 2004, the HHS Task Force on Drug Importation issued a Report on Prescription Drug Importation providing a comprehensive overview of its safety and cost findings. Although the final rule states that section 804 can now be implemented in a manner consistent with the certification criteria, the statement is based mainly on general assertions that Canada has increased its oversight of both pharmaceutical manufacturing practices and supply chain participants. The final rule makes no specific findings relating to cost.

The final rule implements the section 804 commercial importation provisions through time-limited Section 804 Importation Programs ("SIPs"), which will be authorized by FDA and managed by states (including territories) and Indian Tribes. A summary of key provisions relating to SIP proposals, the importation process, and labeling of imported drugs is provided below.

A. SIP Proposals

Under the final rule, a state or Indian Tribe can submit a SIP proposal to FDA along with any co-sponsors, which can include other non-federal government entities, pharmacists, and wholesalers. The SIP Sponsor must specify the eligible prescription drugs that will be included in the SIP. An eligible prescription drug is a drug that has been approved by the Health Products and Food Branch of Health Canada ("HPFB"), and, but for the fact that it deviates from the required U.S. labeling, also "meets the conditions" in an FDA-approved new drug application ("NDA") or abbreviated new drug application ("ANDA") for a drug that is commercially marketed in the United States. Further, an eligible prescription drug cannot be a controlled substance, a biological product (as defined in section 351 of the Public Health Service Act), an infused drug, an intravenously injected drug, or a drug that is inhaled during surgery, an intrathecally injected drugs or intraocularly injected drugs, or a drug that is subject to risk evaluation and mitigation strategies ("REMS").

The SIP Sponsor must identify the SIP participants, including the Foreign Seller in Canada that will purchase the eligible prescription drug directly from the manufacturer and the Importer in the United States that will buy the drug directly from the Foreign Seller. The SIP proposals also must include a summary of how the SIP Sponsor will ensure, among other things, that:

- The supply chain is secure;
- The labeling requirements of the FDCA are met;
- The post-importation pharmacovigilance and other FDCA requirements are met; and
- The SIP will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs that the SIP Sponsor seeks to import.

FDA may decline to authorize the SIP proposal for failure to meet the requirements of the rule. FDA may also decide not to authorize an SIP proposal that meets the requirements because of potential safety concerns or uncertainty that the proposal would adequately protect the public health. Authorization for SIPs will terminate automatically after 2 years, unless an extension is granted or the authorization specifies a shorter period of time. FDA can also terminate an SIP "at any time" for failure to meet certain requirements under the rule or "under any other circumstances in FDA's discretion."

B. Importation Process

The final rule describes the process for importing eligible drugs under a SIP. 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. Notably, the pre-import request must include an attestation and information statement from the manufacturer that establishes that the drug proposed for import, but for the fact that it bears the HPFB-approved labeling, meets the conditions in the FDA-approved NDA or ANDA. The manufacturer must provide the attestation and information statement within 30 calendar days of receiving the Importer's request or notify FDA and the Importer of its inability to do so and provide the reasons why.

Either the manufacturer or the Importer must conduct statutorily-mandated testing for authenticity, degradation, and compliance with established specifications and standards ("Statutory Testing"). If the Importer conducts Statutory Testing, the manufacturer must provide the Importer with the information needed to authenticate the drug and confirm that the labeling complies with requirements under the FDCA. Under the final rule, FDA will not provide manufacturer information to the importer if the manufacturer declines to do so, though FDA emphasizes the criminal penalties manufacturers could face if they do not comply with required disclosures.

Post-importation, Importers must submit adverse event, field alert, and other reports to FDA and to the manufacturer. The SIP Sponsor is responsible for effectuating recalls. Each SIP Sponsor is also required to provide FDA with data and information about its SIP, including the SIP's cost savings to the American consumer.

C. Labeling of Imported Drugs

According to the final rule, the imported drug must meet the FDCA's labeling requirements and use the FDA-approved labeling under the applicable NDA or ANDA, with certain exceptions. The final rule has removed the proposed reference to cost from the required labeling for drugs

imported under a SIP. The proposed rule would have required labeling for imported drugs to include a disclosure that the drug was imported from Canada "to reduce its cost to the American consumer." In addition, the final rule requires a statement in the labeling that the drug was imported from Canada without the authorization of the manufacturer and requires subject drugs to bear a new National Drug Code ("NDC").

III. Request for Proposals on Personal Importation

HHS issued an RFP for individuals to import prescription drugs through authorized State-licensed pharmacies under section 804(j)(2) of the FDCA. Once section 804 is effective, section 804(j)(2) authorizes the Secretary to grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug. The RFP acknowledges that this framework for importation by individuals can be implemented only if the Secretary certifies to Congress that the importation will pose no additional risk to the public's health and safety and result in a significant reduction in the cost of covered products to the American consumer.

Notably, in the 2004 HHS Task Force Report, HHS and FDA determined that it would be extraordinarily difficult and costly for personal importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs. In addition, in the December 2019 proposed rule, FDA proposed not to implement the personal importation provisions in section 804(j) because of the risks to patient safety, including risks from medications ordered from online pharmacies and imported through international mail, express couriers, and other means. The RFP states that this pathway would not authorize individuals to purchase prescription drugs through the Internet, directly from a foreign pharmacy, or from any other foreign seller.

The RFP also seeks proposals for Individual Waiver Importation Plans ("IWIPs") under which authorized state-licensed pharmacies could dispense prescription drugs imported from an "Acceptable Foreign Source" to individuals who present in-person a valid section 804(j)(2) waiver issued by HHS. Australia, Canada, the European Union or a country in the European Economic Area, Israel, Japan, New Zealand, Switzerland, South Africa, and the United Kingdom are each an "Acceptable Foreign Source."

The sponsor of the plan may be an interested person, including a distributor, wholesaler, or pharmacy. The application should identify the specific FDA-approved prescription drugs that individuals would be able to import. It also should outline a program with controls sufficient to ensure that the IWIP will pose no additional risk to the public's health and safety and would result in a significant reduction in the cost of the covered products to the American consumer. The plan should propose a waiver verification process with its IWIP application. The plan also should address the following issues:

- maintaining supply chain security;
- ensuring that each IWIP drug is FDA-approved was made in an FDA-registered facility;
- ensuring the labeling of each IWIP drug comports with the labeling of its U.S.-approved counterpart;
- ensuring that the IWIP drug does not enter standard U.S. wholesaler-pharmacy distribution channels in the United States;
- identifying the specific U.S. pharmacies; and

- any other applicable legal requirements.

HHS and FDA will review IWIP applications to determine whether the required showing is made. HHS will establish a process and an electronic portal by which individuals seeking to import prescription drugs through an authorized IWIP can seek, on a case-by-case basis, section 804(j)(2) waivers.

III. Request for Proposals on Insulin Re-Importation

HHS issued an RFP seeking proposals whereby insulin manufactured in the United States and exported to foreign countries can be reimported into the United States by entities other than the manufacturer under section 801(d) of the FDCA. Section 801(d)(1)(A) provides that no prescription drug or drug composed wholly or partly of insulin which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug, except as provided in section 801(d)(2) and section 804, discussed above. Section 801(d)(2) states that the HHS Secretary may authorize the importation of a drug, the importation of which is prohibited by (d)(1)(A), which includes insulin and other biologics, if "the drug is required for emergency medical care."

The Insulin RFP asserts that high insulin prices have led patients to ration their insulin, and that such rationing leads to poor health outcomes, including diabetic ketoacidosis and in some cases death. The RFP states that "the Secretary has concluded that the widespread rationing of insulin constitutes an emergency, that insulin is required for emergency medical care, and that insulin should be available to the American people through authorized reimportation programs."

HHS and FDA plan to begin accepting applications immediately and will evaluate whether a proposal adequately addresses public health concerns and insulin product considerations when deciding whether to approve the application.

IV. Final Guidance on Importation of Certain FDA-Approved Drugs

FDA issued Final Guidance for Industry on importation of certain FDA-approved drugs by manufacturers. The guidance finalizes the December 2019 draft guidance and describes procedures for manufacturers to obtain a NDC for products, including biological products and combination products, originally manufactured and intended for sale abroad under section 801(d)(1)(B) of the FDCA. The stated goal of the final guidance is to "provide an additional avenue through which drugs could be sold at a lower cost in the U.S. market."

Consistent with the draft guidance, the final guidance discusses how a manufacturer could import a "multi-market approved product" (or an "MMA" product). An MMA product is an FDA-approved prescription drug or FDA-licensed biological product approved in an NDA or Biologics License Application ("BLA") that: (1) was originally manufactured outside the U.S. and is authorized for marketing for another country's regulatory authority; (2) is the subject of a supplement to an approved NDA or BLA; (3) is imported into the U.S. and is authorized by the manufacturer to be marketed in the U.S.; (4) meets the quality standards in the approved application for marketing in the U.S.; (5) continues to meet the quality standards for marketing in its originally intended market; and (6) differs from the FDA-approved drug or FDA-licensed biological product only with regard to a labeling statement.

The final guidance also provides that an MMA product may include a combination product approved in an NDA or BLA (as defined under 21 C.F.R. Part 3), and must meet the quality standards in the approved application for marketing in the U.S. The MMA product must have

the same formulation, manufacturing process and specifications for the active ingredients and drug product as in the chemistry, manufacturing, and controls ("CMC") section of the approved application. To meet the specifications of the application holder's existing NDA or BLA, an MMA drug product must be manufactured, packaged, labeled, and tested at the facility approved in the application, including specific sites, product lines, and quality systems.

The final guidance provides recommendations for manufacturers to import an MMA product into the U.S. Specifically, FDA recommends that the manufacturer submit a labeling supplement supported by an attestation that the MMA product conforms to the product described in the approved application, obtain a new labeler code for the NDC of the MMA product, use a container label with features that make the MMA product easily distinguishable from the non-MMA product, add a reference to the FDA guidance in the MMA product labeling, and issue a Dear Healthcare Provider Letter upon approval of a supplement of an MMA product.

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