

REQUEST FOR PROPOSALS REGARDING WAIVERS FOR INDIVIDUAL PRESCRIPTION DRUG IMPORTATION PROGRAMS

The Trump Administration has taken action, and is continuing to take action, to lower the cost of prescription drugs. As part of this effort, pursuant to President Trump's July 24, 2020 Executive Order, the Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA) requests proposals to create and operate new pathways for individuals to import prescription drugs through authorized State-licensed pharmacies.

I. Description of the Program

Under this pathway, individuals in the United States who have obtained waivers from the Secretary would be able to import certain FDA-approved prescription drugs from Australia, Canada, the European Union or a country in the European Economic Area, Israel, Japan, New Zealand, Switzerland, South Africa, or the United Kingdom (each an "Acceptable Foreign Source"). Prescription drugs in the program will ultimately be dispensed to patients through authorized State-licensed pharmacies. These pharmacies would be specified in authorized Individual Waiver Importation Plans (IWIPs). This pathway would not authorize individuals in the United States to purchase prescription drugs through the Internet, directly from a foreign pharmacy, or from any other foreign seller.

Section 804(j)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) permits the Secretary to grant individuals a waiver of the prohibition of importation of a prescription drug or device, or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate. Under the programs described herein, the Secretary may grant waivers to individuals who seek to import prescription drugs for personal use. Under these programs, the individual will obtain the imported prescription drugs from an authorized State-licensed pharmacy through an authorized IWIP. State-licensed pharmacies operating under an authorized IWIP would be permitted to dispense an FDA-approved prescription drug imported from an Acceptable Foreign Source (referred to in this request for proposals as an "IWIP drug") to an individual only upon presentation in-person of a valid section 804(j)(2) waiver issued by HHS.

For the Secretary to issue a waiver for an IWIP drug, the plan sponsor, which may be any interested person (including a distributor, wholesaler, or pharmacy) would submit to the Secretary an application identifying the specific FDA-approved prescription drugs that individuals would be able to import. The plan sponsor's submission should also 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. In making this showing, the application should address the following issues:

- **Maintain supply chain security and safety** to help protect consumers from exposure to products that may be counterfeit, stolen, contaminated, or otherwise harmful;

- **Ensure that each IWIP drug is FDA-approved and was made in a FDA-registered facility;**
- **Ensure that the labeling for each IWIP drug comports with the labeling of its U.S.-approved counterpart** except to identify the product as having been imported subject to an authorized IWIP;
- **Ensure that the IWIP drug does not enter standard U.S. wholesaler-pharmacy distribution channels in the United States.** The IWIP drugs shall not be commingled with U.S. prescription drugs that are not imported, and patients should be aware that the prescription drugs they receive through the program are imported from abroad;
- **Identify the specific U.S. pharmacies** that would be authorized to dispense the IWIP drug in-person or via mail-order to patients in the United States with valid prescriptions and valid 804(j)(2) waivers, and ensure that the U.S. pharmacies do not transfer the IWIP drug from one pharmacy to another; and
- **Address any other applicable legal requirements.**

The plan sponsor may request a variance from the scope of this proposal, provided such variance is consistent with applicable law. HHS and FDA will review IWIP applications to determine whether the required showing has been made. Proposals should be sent to import@hhs.gov. HHS and FDA will be accepting proposals beginning on September 24, 2020 and continuing indefinitely. The Secretary intends to periodically reexamine authorized IWIPs and may revoke the authorization if the criteria are no longer met or for other reasons, provided that the Secretary will give due consideration for the reliance interests of patients and their health care providers.

Consistent with section 804(a)(3) of the FD&C Act, the following categories of prescription drugs will be excluded from importation under this program: controlled substances, biological products, infused drugs, intravenously injected drugs, intrathecally injected drugs, drugs inhaled during surgery, and parenteral drugs.

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 from the Secretary.

The plan sponsor should propose a waiver verification process with its IWIP application. That process should include a mechanism the plan sponsor will use to verify the authenticity of any waiver an individual receives from the Secretary allowing for personal importation of prescription drugs.

Pursuant to section 804(l) of the FD&C Act, 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. The Secretary must be adequately satisfied that these requirements are met in order to make the certification.

This request for proposals does not constitute final agency action or a final order.

Dated: September 24, 2020 (updated January 12, 2021)