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FDA: Major Policy Shift Authorizes Florida's Plan to Import Drugs from Canada

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On Friday, January 5, 2024, in a major policy shift**,** the U.S. Food & Drug Administration (FDA) authorized Florida's Agency for Health Care Administration's plan to purchase medicines in bulk for its Medicaid programs, government clinics, and prisons from Canadian wholesalers. FDA determined that Florida demonstrated that it meets the statutory obligation to ensure that importation under section 804 of the Federal Food, Drug and Cosmetic Act will significantly reduce the cost of covered products to the American consumer without posing additional risk to the public's health and safety. FDA authorized this importation plan for a period of two years.

Florida will still have to address numerous requirements and overcome significant hurdles before the state can begin to import any Canadian drugs. Thus, there are potential impediments that Florida will likely face, *before* importing any Canadian drugs, such as burdensome administrative requirements, potential litigation, and other legal and regulatory challenges actions that might be taken by pharmaceutical companies and other interested parties that could muddle, hold up, and, perhaps prevent the importation of drug from Canada.

Requirements for Importation

The Importer, is this case, the state of Florida, is required to submit a Pre-Import Request to FDA at least 30 calendar days before the import. An eligible prescription drug may not be imported or offered for import under 21 C.F.R. Part 251 unless the Importer has filed and FDA has granted the Pre-Import Request.

This Pre-Import Request is required to include details about, among other things:

1. The foreign seller that will purchase the prescription drug directly from its manufacturer, along with invoices, batch, and lot/control numbers to verify the sale and the units sold. There must be a Canada-licensed wholesaler that is also registered with FDA as a foreign seller.
2. The Importer that will purchase the prescription drug directly from the foreign seller, along with invoices, batch, and lot/control numbers to verify the sale and the units sold. This must be a U.S.-based entity licensed as a wholesale distributor or a pharmacist that will import the drugs.
3. A description of each eligible drug covered by the Pre-Import Request. This includes the

name and identity of the Health Canada-approved drug; information about the active pharmaceutical ingredient (API) manufacturer; and information about the manufacturer of the eligible prescription drug.
4. The FDA-approved counterpart drug and New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) number, and an attestation and information statement from the manufacturer that the drugs meet the conditions in the FDA-approved NDA or ANDA (including current Good Manufacturing Practice (cGMP) compliance).
5. A plan to test the drugs, as required by section 804(e), including for authenticity, degradation, and to ensure compliance with the established specifications and standards.
6. Proposed relabeling and proposed NDC numbers for the drugs to be imported.
7. Information about the facility where the relabeling and/or repackaging will occur for the eligible prescription drug.
8. Information related to the importation (e.g., date, location, warehouse).

Florida has 12 months to submit a Pre-Import Request. FDA would need at least 30 days to review each Pre-Import Request. The US government requires at least another 30 days to examine the shipment at the U.S. Customs and Border Protection (CBP) port of entry.

Additional Requirements

Florida will also have to demonstrate to FDA that, as the Section 804 Importation Programs (SIP) sponsor, it is able to effectively implement all aspects of the plan that FDA has authorized, including requirements for manufacturers, foreign sellers, importers, and qualifying laboratories, including:

- Registration of foreign sellers;
- Reviewing and updating registration information for foreign sellers;
- Official contact and U.S. agent for foreign sellers;
- Supply chain security requirements for eligible prescription drugs;
- Qualifying laboratory requirements;
- Laboratory testing requirements;
- Importation requirements; and
- Post-importation requirements.

Legal Hurdles

There will likely be litigation challenging FDA’s authorization of the Florida SIP proposal and FDA’s denial on January 5, 2024, of the Citizen Petition submitted by PhRMA and others requesting that FDA should not authorize Florida’s SIP proposal.

The Canadian government, in the effort to protect the health and safety of its citizens, may challenge the program to preserve the integrity of the supply chain and prevent drug shortages in Canada.

It may be very difficult for Florida officials to identify, qualify, and maintain foreign suppliers who are willing and able to sell drugs for export to the U.S. under a SIP. Drug companies will try to limit or prevent drug products to be exported from Canada. Again, the health and safety of Canadian patients are of primary importance and will not likely be jeopardized, especially if there is not a sufficient supply of products for Canadian citizens.

Conclusions

While The FDA has approved Florida’s program to import drugs from Canada, there are numerous requirements that have to be met before any such importation can begin. In addition, there are likely to be significant legal challenges that could delay and possibly prevent the program from moving forward for a long time.

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