



## **ASOP Canada Statement on the U.S. Food and Drug Administration approval of State of Florida Section 804 Importation Program**

TORONTO January 5, 2024 – In response to the Food and Drug Administration’s approval of Florida’s Section 804 Importation Programs (SIP) allowing for bulk drug importation from Canada:

“The Alliance for Safe Online Pharmacies (ASOP) Canada has long been opposed to U.S. government proposals to import medicines from Canada, due to their potential impact on Canada’s drug supply. We are concerned that U.S. FDA approval of Florida’s state importation program creates an unnecessary risk at a time where Canada continues to suffer from drug shortages for a range of life-saving medications.

We applaud Canada’s government for taking steps to protect our drug supply in response to the U.S. FDA Final Rule that allows for importation of certain prescription medications from Canada. Health Canada [issued regulations](#) in August 2021 to stipulate that distribution for pharmaceuticals intended for the Canadian market will not cause or exacerbate a shortage of a drug. In light of the U.S. FDA’s Florida decision, we encourage the Government of Canada to reevaluate its regulation to ensure that all necessary processes and procedures are in place to prevent the creation or exacerbation of drug shortages in Canada.

In the past, ASOP Canada together with 14 other organizations, has raised concerns to Canada’s Prime Minister<sup>1</sup> and Health Minister<sup>2</sup> regarding U.S. importation proposals, and their impact on Canada’s drug supply. Our drug supply is meant for Canadians, not a country with a population 10 times our size.

In addition to the impact that importation could have on Canada’s drug supply, ASOP Canada fears that importation of Health Canada-approved medication by the U.S. could potentially drive Canadian and American patients to look for medicine through unconventional sources, like unlicensed, illegal internet pharmacies that often distribute counterfeit, substandard or unapproved drugs.

We look forward to working together with our members and the Government of Canada to ensure U.S. state importation plans do not drain Canada’s critical drug supply to the United States.”

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<sup>1</sup> [https://buysaferx.pharmacy/wp-content/uploads/2019/11/Multi-Stakeholder-Letter-to-PM-Trudeau.Final\\_.110619.pdf](https://buysaferx.pharmacy/wp-content/uploads/2019/11/Multi-Stakeholder-Letter-to-PM-Trudeau.Final_.110619.pdf)

<sup>2</sup> [https://buysaferx.pharmacy/wp-content/uploads/2019/07/Health-Canada-Stakeholder-Letter\\_Importation.Minister.FINAL072519.pdf](https://buysaferx.pharmacy/wp-content/uploads/2019/07/Health-Canada-Stakeholder-Letter_Importation.Minister.FINAL072519.pdf)