



Healthcare Distribution Alliance

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<https://www.regulations.gov/docket/FDA-2021-P-0034>

May 28, 2021

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Citizen Petition, Importation of Prescription Drugs Final Rule, Dkt. No. FDA-2021-P-0034

Dear Sir/Madam:

The Healthcare Distribution Alliance (HDA) thanks the Food and Drug Administration (FDA) for this opportunity to submit comments in support of the Citizen Petition submitted jointly by the Pharmaceutical Research and Manufacturers of America (PhRMA), the Partnership for Safe Medicines (PSM), and the Council for Affordable Health Coverage (CAHC), Dkt. No. FDA-2021-P-0034 (Citizen Petition). The Pharmaceutical Distribution Security Alliance (PDSA) has submitted comments in support of the Citizen Petition (see comment [here](#)); HDA is a member of PDSA and joined in and supports that organization's comment as well.

HDA represents primary pharmaceutical distributors – the vital link between the nation's pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDA members serve as the central link in a sophisticated national supply chain. HDA members take this mission very seriously, and we support manufacturers, healthcare providers, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated.

The Citizen Petition asks FDA to refrain from authorizing the Section 804 Importation Program (SIP) Proposal for the Importation of Prescription Drugs from Canada submitted by the State of Florida ("Florida SIP Proposal" or "Proposal"). The Florida SIP Proposal was submitted pursuant to a new final Section 804 Importation Program regulation, contained within [21 C.F.R. Part 251](#), which went into effect on November 30, 2020.¹ A SIP allows for the importation of certain prescription drugs from Canada. Petitioners presented compelling arguments for how approval of the Florida SIP proposal would be contrary to federal law and would allow for adulterated, misbranded, counterfeit, and otherwise substandard prescription drugs products to enter the U.S. pharmaceutical supply chain. Petitioners state that approval of the Florida SIP Proposal would endanger the health and safety of Americans who rely upon a secure, closed system for the

¹ See, <https://www.govinfo.gov/content/pkg/FR-2020-10-01/pdf/2020-21522.pdf>.

distribution of pharmaceuticals. We agree with the Petitioners and do not believe HHS can make the required statutory certification under Section 804 of the Federal Food, Drug and Cosmetic Act (FDC Act) that the approval of a SIP would “pose no additional risk to the public’s health and safety.”

Of particular concern to HDA is that approval of the Florida SIP Proposal undermines the protections implemented in the Drug Supply Chain Security Act (DSCSA) and the enormous investment that wholesale distributors and other authorized trading partners have made to implement this critical amendment to the FDC Act. The DSCSA included multiple requirements designed to further secure the supply chain. Among them were steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. This law provides a federal traceability solution for prescription medicines, which by 2023, will lead to the establishment of electronic, unit-level traceability requirements across the entire supply chain for prescription drug products.

At a public meeting in February 2018, then FDA Commissioner Gottlieb discussed DSCSA implementation, the challenges of securing the U.S. pharmaceutical supply chain, and why the law’s protections were so important to protecting American patients.

Every link in [the pharmaceutical supply] chain must be secure: From the moment finished drug products leave manufacturing facilities to final delivery to pharmacies or providers’ offices where medicines are ultimately dispensed to patients. ... While the U.S. drug supply chain is among the safest in the world, complacency isn’t an option. ... ***If we tolerate a single weak link in the system, they’ll find it.***² (emphasis supplied)

We believe approval of the Florida SIP Proposal would create weak links in the U.S. closed system of pharmaceutical distribution and new vulnerabilities in the supply chain.

We are especially concerned with how approval of the Florida SIP Proposal, and others that will likely follow,³ will undermine key provisions of the DSCSA which mandate the interoperable, electronic system for the exchange of data in accordance with widely recognized, international standards⁴ and the federally mandated, preemptive, uniform national policy for the tracing of pharmaceuticals and the licensure of wholesale distributors.⁵ Prior to the DSCSA, States were free to develop their own requirements for pharmaceutical tracing and trading partner licensure that varied widely in their breadth, protectiveness, and stringency. In the view of Congress and stakeholders, this 50-state patchwork was vulnerable to exploitation – creating too many of the “weak links” that former Commissioner Gottlieb warned of.⁶

² [Commissioner Gottlieb, Remarks on Enhancing Drug Distribution Security, February 28, 2018.](#)

³ We note that another Citizen Petition, challenging the SIP Proposal submitted by the State of New Mexico, has also been filed, [Dkt. No. FDA-2021-P-0307](#).

⁴ See, e.g., § 582(a)(2)(A).

⁵ See, e.g., § 585, Uniform National Policy.

⁶ In fact, Petitioners have submitted a new Citizen Petition regarding the State of New Mexico’s proposed SIP. Dkt. No. FDA-2021-P-0307 available [here](#).

Individually developed, submitted, and approved SIPs turn back the clock and undo the beneficial uniformity Congress mandated in the DSCSA. Each SIP approved will bring back pre-DSCSA inconsistency, a patchwork of 50 or more different pharmaceutical supply chains.

Moreover, the importation regulations are premised upon a deeply flawed assumption – that importation of unapproved drugs from Canada can be done securely because of the DSCSA’s wholesale distributor licensure requirements. Under the import regulations, the SIP must identify a licensed wholesale distributor or pharmacy as the importer.⁷ Under the DSCSA, FDA was required to issue “national standards” for the licensure of wholesale distributors by November 27, 2015 that would, in turn, be adopted by State licensing authorities⁸ to help ensure rigorous oversight of wholesale distributors and national, uniform regulation of their activities.

However, these state licensure standards have been neither promulgated nor implemented, and are now over five years late. It is deeply concerning that the importation of unapproved drugs from Canada places such great reliance upon the licensure of wholesale distributors pursuant to the DSCSA, when a key element of that oversight, the uniform national licensure standards that are mandated by law, has yet to materialize.

* * *

In conclusion, HDA appreciates this opportunity to support the Citizen Petition. We agree with the petitioners that approval of the Florida SIP Proposal would endanger the health of Americans and make the U.S. pharmaceutical supply chain less safe and secure.

If you have any questions, please feel free to contact me at aducca@hda.org or 703-885-0240. Thank you.

Sincerely,



Anita T. Ducca
Senior Vice President, Regulatory Affairs

⁷ See, e.g., 21 C.F.R. § 251.2 (definition of “importer”).

⁸ See: § 583(a) (“National Standards for Prescription Drug Wholesale Distributors”).