APhA
American Pharmacists Association

Via Electronic Submission to: www.regulations.gov

April 1, 2021

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2021-P-0034

Dear Sir or Madam:

The American Pharmacists Association (APhA) appreciates the opportunity to submit our comments to the Food and Drug Administration (FDA) in support of the citizen petition filed by the Pharmaceutical Research and Manufacturers of America, the Partnership for Safe Medicines, and the Council for Affordable Health Coverage urging the agency to refrain from approving Florida's Section 804 Importation Program (SIP) Proposal.[1] While APhA supports efforts to lower prescription drug costs for American patients, Florida's SIP Proposal highlights myriad reasons why the Final Rule permitting commercial importation of prescription drugs is inherently flawed. Among these are the additional risks posed to public health and safety, as well as the baseless presumption of significant cost savings to the American consumer.

Founded in 1852, APhA represents pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use, advancing patient care, and protecting public health. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

[1] Pharmaceutical Research and Manufacturers of America, Partnership for Safe Medicines, and Council for Affordable Health Coverage, Docket No. FDA-2019-N-5711 (Jan. 7, 2021), available at https://downloads.regulations.gov/FDA-2021-P-0034-0001/attachment_1.pdf.

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Deficiencies in Florida's SIP Proposal Render It Unapprovable

As stated in the citizen petition, Florida's Proposal lacks many items required for FDA approval of a Section 804 Importation Program:

Lack of Identification of the Foreign Seller

Perhaps the Florida Proposal's most glaring omission is not naming the Foreign Seller. As we stated in our March 9, 2020 comments on the Importation proposed rule,[2] APhA and our members are very concerned about the lax oversight and accountability of the Foreign Seller's role in the SIP importation process. Introducing imported drugs into the market is a daunting enough task that requires significant oversight even with clarity as to the identity of the Foreign Seller. Not naming a Foreign Seller not only adds to confusion and lack of transparency, but also renders Florida's Proposal disqualified by law, as pointed out by the citizen petition. The identity of the Foreign Seller is crucial information that must be in place before FDA can approve a SIP proposal.[3]

Failure to Meet the Requirements in the Federal Food, Drug, and Cosmetic Act Designed to Protect Patients

Florida's Proposal fails to meet the requirements in the Federal Food, Drug, and Cosmetic Act (FDCA) designed to protect patients, including the following:

- Poor assurances of transportation, storage, repackaging, and relabeling in compliance with CGMP requirements; and
- Insufficient detail and clarity as to product testing and supply chain security.

Florida's Proposal lacks assurances that imported drugs will be appropriately transported, stored, repackaged, and relabeled. Before furnishing medications and counseling to patients, pharmacists rely on the assumption that all drug products meet specifications that assure safety, efficacy, and quality, including that they are manufactured, distributed, stored, and handled in compliance with appropriate standards. However, if pharmacists are not able to ensure that basic trust, we cannot effectively fulfill our oath[4] to ensure optimal drug therapy outcomes.

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[2] APhA comments to FDA on "Importation of Prescription Drugs; Proposed Rule; Docket No. FDA-2019-N-5711" (March 9, 2020), available at https://aphanet.pharmacist.com/sites/default/files/APhA_Drug_Importation_Proposed_Rule_FINAL.pdf

[3] See 21 C.F.R. § 251.4.

[4] APhA Oath Of A Pharmacist, available at https://pharmacist.com/About/Oath-of-a-Pharmacist

APhA also agrees with the citizen petition's concerns regarding a lack of detail on supply chain security measures and increased risks of unapproved, misbranded, or otherwise adulterated drugs being introduced into the U.S. market.

Inappropriate Delegation of Responsibilities to LifeScience Logistics

Florida's Proposal inappropriately delegates certain responsibilities of the State, such as identifying the Foreign Seller and manufacturers and negotiating prices, to a private company, LifeScience Logistics, LLC ("LSL"). APhA is concerned that LSL adds yet another link in the supply chain, thus increasing the risk to public health and safety. Furthermore, we have serious concerns about the ability of LSL to handle recalls and returns, since it is unlikely that LSL, as a third-party logistics provider, has experience implementing them.

Failure to Demonstrate Significant Cost Savings to American Consumers

One of the primary requirements of Section 804 is that there must be a clear demonstration of significant cost savings to American consumers. As outlined in the citizen petition, Florida's Proposal simply focuses on *purported* savings to the State and fails to demonstrate significant cost savings to consumers.

As APhA stated in our previous comments,[5] as a result of additional steps in the supply chain, such as relabeling (twice) and laboratory testing requirements, it is highly unlikely that there will be significant cost savings to consumers. The need for additional track and trace, recall, and adverse event reporting systems will further increase the costs associated with the importation program – thus negating any potential cost benefits to patients. Unknown, unproven cost savings do not justify jeopardizing U.S. supply chain integrity and patient safety.

Florida's proposal estimates that the State will recognize $80 million to $150 million in savings in the first year, and over $150 million in subsequent years. However, the proposal does not explain how these figures were calculated, nor provide an explanation for the $70 million range in potential savings. While there is a table listing six HIV/AIDS drugs and presenting the estimated difference between the total spend in Q1 2018 and the potential spend,[6] there is no justification for the State's extrapolation of $150 million in annual cost savings. This analysis

[5] See APhA comments to FDA on "Importation of Prescription Drugs; Proposed Rule; Docket No. FDA-2019-N-5711" (March 9, 2020) p. 12, available at https://aphanet.pharmacist.com/sites/default/files/APhA_Drug_Importation_Proposed_Rule_FINAL.pdf

[6] Florida Proposal at 22.

lacks the rigor necessary to validate meaningful cost savings that would support importation. APhA urges FDA not to approve Florida's proposal or any SIP Program without a thorough cost analysis, including hard data supporting markup and cost savings estimates.

APhA Continues to Oppose FDA's Final Importation Rule

APhA continues to oppose FDA's final importation rule. The final rule jeopardizes patient safety by creating supply chain vulnerabilities that could potentially introduce counterfeit or unsafe drugs into the market. It also undermines the Drug Supply Chain Security Act (DSCSA), which creates "track-and-trace" safeguards that do not exist in Canada. By commingling FDA-approved and imported versions in the marketplace, this program also creates pharmacy operation disruptions and product selection confusion and may limit patient access to medications by complicating insurance coverage and reimbursement at the pharmacy. APhA strongly urges FDA to reject Florida's SIP Proposal and end this program of unsafe drug importation schemes that would allow the introduction of risky products into our secure U.S. drug supply chain.

Thank you for the opportunity to submit these comments in support of this citizen petition. If you have any questions or require additional information, please contact Karin Bolte, JD, Director, Health Policy, at kbolte@aphanet.org or by phone at (202) 558-2727.

Sincerely,

Ilisa BG Bernstein

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Senior Vice President, Pharmacy Practice and Government Affairs