November 6, 2026

Shevaun Harris, Secretary
Florida Agency for Health Care Administration
2727 Mahan Drive, Bldg. 3 Mailstop 1
Tallahassee, FL 32308

Re: Letter of Fifth Authorization Extension for Florida's Section 804 Importation Program

Dear Secretary Harris:

On January 5, 2024, based on FDA's review of your November 16, 2023 Section 804 Importation Program (SIP) proposal[1] and clarifying communications,[2] FDA determined that your SIP proposal met the requirements of section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) and FDA's implementing regulations at 21 CFR part 251, and therefore you demonstrated that it met the statutory obligation to ensure that importation under section 804 will significantly reduce the cost of covered products to the American consumer without posing additional risk to the public's health and safety.

As indicated in our October 25, 2024, letter and follow-up e-mails, under FDA's regulations, the authorization of Florida's SIP would end on January 5, 2025, unless Florida's Importer files an electronic import entry for consumption for a shipment of eligible prescription drugs under the SIP on or before that date (21 CFR 251.6(c)). On December 20, 2024, FDA granted a 6-month extension (i.e., until July 6, 2025) of Florida's Agency for Health Care Administration's existing SIP Authorization (21 CFR 251.4) based on our understanding that you continued to be committed to moving forward with the next steps for launching your SIP. In response to the extension letter issued on December 20, 2024, Florida's Agency for Health Care Administration requested additional extensions which FDA granted for additional extensions on June 2, 2025, November 7, 2025, and May 6, 2026 (i.e., until November 6, 2026).

FDA is granting an additional 6-month extension for you to begin implementing your SIP (i.e., until May 6, 2027).

This extension of your existing SIP authorization is based on our understanding that there have been no material changes to your SIP except the specified change of a responsible individual, from Secretary Jason Weida to Secretary Shevaun Harris that you conveyed to FDA via email on May 6, 2025. Under FDA's regulations, "[a] SIP Sponsor must not make any changes or permit any changes to be made to a SIP without first securing FDA's authorization" (21 CFR 251.8(e)). We note that FDA may revoke authorization of a SIP, in whole or in part, including with respect to one or more drugs in the SIP, at any time if FDA determines that "the SIP no longer meets the requirements of section 804 of the Federal Food, Drug, and Cosmetic Act, this

[1] The SIP proposal was initially submitted by the Florida Agency for Health Care Administration to the FDA on November 23, 2020, and subsequently revised on: April 19, 2021, September 15, 2021, November 15, 2021, April 21, 2023, and October 20, 2023.
[2] The Florida Agency for Health Care Administration sent clarifying communications via email on October 27, 2023, November 16, 2023, and May 6, 2024.

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part, or the SIP, including, among other things, if FDA finds that the manufacturer, the Foreign Seller, the Importer, or any other supply chain participant is found to be not compliant with section 501(a)(2)(A) or (B) of the Federal Food, Drug, and Cosmetic Act" (21 CFR 251.7(c)(3)).

Before importation can occur, a Pre-Import Request must be filed by the Importer and granted by FDA in accordance with § 251.5. Once a Pre-Import Request is granted, the Importer, or its authorized customs broker, may file an electronic import entry for consumption for a shipment of eligible prescription drugs under the authorized SIP. An article that is imported or offered for import into the United States in violation of section 804 of the FD&C Act or 21 CFR part 251 is subject to refusal under section 801 of the FD&C Act (21 CFR 251.21(a)). The importation of a prescription drug in violation of section 804 of the FD&C Act; the falsification of any record required to be maintained or provided to FDA under section 804; or any other violation of 21 CFR part 251 is a prohibited act under section 301(aa) of the FD&C Act (21 CFR 251.21(b)).

We recommend that you stay up to date on relevant FDA requirements, including those that are referenced in 21 CFR part 251, and any associated FDA guidance on such requirements. We encourage you to bring any questions you may have to FDA's Office of Drug Security, Integrity, and Response, Division of Global Drug Distribution via the mailbox at: SIPDrugImportsandRFP@fda.hhs.gov.

Sincerely,

SANGEETA CHATTERJEE -S

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Sangeeta Vaswani Chatterjee, Pharm.D.
Director
Office of Drug Security, Integrity, and Response
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