U.S. FOOD & DRUG ADMINISTRATION

June 2, 2025

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

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

Dear Secretary Harris:

FDA is committed to continuing to work with states, such as Florida, and Tribes that propose to develop Section 804 Importation Programs (SIPs) in accordance with section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) and FDA's implementing regulations. As you know, on January 5, 2024, based on FDA's review of your November 16, 2023 SIP proposal[1] and clarifying communications,[2] FDA determined that your SIP proposal met the requirements of section 804 and 21 Code of Federal Regulations (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.

[redacted (b) (4)] 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.[3] In response to the extension letter issued on December 20, 2024, Florida's Agency for Health Care Administration has now requested an additional extension on May 6, 2025. FDA is therefore granting an additional extension for a period of 4 months (i.e., until November 6, 2025) to follow the previous 6-month extension, [redacted (b) (4)].[5]

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[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] [redacted (b) (4)]

[3] [redacted (b) (4)] /.

[4] See footnote 1, above.

[5] See footnotes 2, above. [redacted (b) (4)]

U.S. Food & Drug Administration
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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. 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 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)).

In response to your May 6, 2025 request to change the responsible individual to Secretary Shevaun Harris, please submit the attestation, a complete disclosure of any past criminal convictions or violations, and a list of all disciplinary actions for Secretary Shevaun Harris pursuant to 21 CFR 251.3(e)(2)-(3) as soon as possible to ensure that subsequent correspondence related to Florida's SIP can be communicated to Secretary Shevaun Harris.

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 and Policy via the mailbox at: SIPDrugImportsandRFP@fda.hhs.gov.

Sincerely,

Sangeeta Chatterjee -S

Digitally signed by Sangeeta Chatterjee -S
Date: 2025.06.02 09:26:37 -04'00'

Sangeeta Vaswani Chatterjee, Pharm.D.
Acting Director, Office of Drug Security, Integrity, and Response
Office of Compliance
Center for Drug Evaluation and Research