U.S. FOOD & DRUG ADMINISTRATION

January 5, 2024

Jason Weida, Secretary
Florida Agency for Health Care Administration
2727 Mahan Drive, Mailstop 1
Tallahassee, FL 32308

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

Dear Secretary Weida:

FDA is committed to continuing to work with states, such as Florida, and Tribes that propose to develop Section 804 Importation Programs (SIP) in accordance with section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) and FDA's implementing regulations. Numerous subject matter experts at FDA and other components of the Department of Health and Human Services (HHS) have carefully and thoroughly reviewed your revised SIP proposal. Based on FDA's review of your most recent SIP proposal that was submitted on November 16, 2023,[1] and clarifying communications,[2] FDA has determined that this SIP proposal meets the requirements of section 804 and 21 CFR part 251, and therefore Florida has demonstrated that it meets 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. FDA is therefore authorizing, for a period of 2 years, Florida's Agency for Health Care Administration's SIP with the labeling corrections specified in the attachment to this letter.[3]

The Importer may now submit a Pre-Import Request to FDA. An eligible prescription drug may not be imported or offered for import under part 251 unless the Importer has filed a Pre-Import Request for that drug, in accordance with 21 CFR 251.5, and FDA has granted the Pre-Import Request. A list of items that "[a] complete Pre-Import Request must include, at a minimum" is specified at 21 CFR 251.5(c). Importation may not proceed until:

[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 communications via email on October 27, 2023 and November 16, 2023.
[3] This time period begins when the Importer, or its authorized customs broker, files an electronic import entry for consumption for its first shipment of eligible prescription drugs under the SIP (21 CFR 251.6(b)). Authorization for the SIP will be terminated if the Importer, or its authorized customs broker, does not file an electronic import entry for consumption for a shipment of eligible prescription drugs under the SIP within 1 year of the date of this letter (21 CFR 251.6(c)).

1. The Importer submits a complete Pre-Import Request to FDA, by email to SIPDrugImportsandRFP@fda.hhs.gov, at least 30 calendar days before the scheduled date of arrival or entry for consumption of a shipment containing an eligible prescription drug covered by the SIP, whichever is earlier. Under 21 CFR 251.17(a) and 21 CFR 1.74(b), the entry for consumption, as defined in 19 CFR 141.0a(f), must be electronically filed in the Automated Commercial Environment (ACE) system for each eligible prescription drug imported or offered for import into the United States. These entries must be filed as formal entries.

   Entry and arrival of a shipment containing an eligible prescription drug is limited under 21 CFR 251.17(b) to the U.S. Customs and Border Protection (CBP) port of entry authorized by FDA (currently the only authorized port is 3801—Detroit)[4]. Once the shipment arrives or is entered at the port of entry, it will be examined by a government agency. Be advised that this process may take longer than 30 calendar days.

   FDA must grant your Pre-Import Request before products may be imported or offered for import. The timeframe necessary for FDA to grant your Pre-Import Request will vary depending on the circumstances of the request—such grant may take more than 30 calendar days. Therefore, it is advisable to submit the Pre-Import Request sooner than the required 30 calendar days.

2. The manufacturer or the Importer conducts testing of the eligible prescription drugs for authenticity, degradation, and to ensure that the eligible prescription drugs are in compliance with established specifications and standards (i.e., Statutory Testing) in accordance with section 804(e)(1) of the FD&C Act. Unless the manufacturer has notified the Importer that it intends to conduct the required testing as provided in 21 CFR 251.16(e), the Pre-Import Request must contain, for each drug covered by the Pre-Import Request, a Statutory Testing plan that includes: (A) a description of how the samples will be selected from a shipment for the Statutory Testing; (B) the name and location of the qualifying laboratory in the United States that will conduct the Statutory Testing; and (C) a description of the testing method(s) that will be used to conduct the Statutory Testing (21 CFR 251.5(c)(4)(xi)).

3. You make the labeling corrections specified in the attachment to this letter. To facilitate the importation process and ensure that the requirements of the FD&C Act and 21 CFR part 251 are met, you should submit the corrected labeling by email to SIPDrugImportsandRFP@fda.hhs.gov for FDA's review prior to the submission of a Pre-Import Request.

In accordance with 21 CFR 251.17(g), after an eligible prescription drug has been shown by testing and relabeling to meet the requirements of section 804 and 21 CFR part 251, the Importer or the manufacturer must provide to FDA the written certification described in section 804(d)(1)(K).

[4] *See* U.S. Customs and Border Protection Cargo Systems Messaging Service bulletin, Nov. 9, 2020, at https://content.govdelivery.com/accounts/USDHSCBP/bulletins/2aabc2f. *See also* FDA Supplemental Guide for the Automated Commercial Environment/International Trade Data System (ACE/ITDS), https://www.cbp.gov/document/guidance/fda-supplemental-guide.

FDA also notes the following, this is not an exhaustive list of all relevant ongoing requirements, and you should consult 21 CFR part 251 for more information:

A Foreign Seller must review and update its registration information in accordance with 21 CFR 251.10.

A SIP Sponsor must submit a report to FDA each quarter in electronic format by email to SIPDrugImportsandRFP@fda.hhs.gov containing the information set forth in FDA's regulations, beginning after the SIP Sponsor files an electronic import entry for consumption for its first shipment of drugs under the SIP (21 CFR 251.19).

A SIP Sponsor may request that FDA extend the authorization period of an authorized SIP (21 CFR 251.8(f)). To be eligible for an extension, a SIP must be up to date on all of the information and records-related requirements of section 804 of the FD&C Act and FDA's regulations. FDA may extend the authorization period for up to 2 years at a time. Such a request must be submitted at least 90 calendar days before the SIP's authorization period will expire.

Additionally, a SIP Sponsor may propose to modify an authorized SIP (21 CFR 251.8). In reviewing a proposal to modify a SIP, among other things, FDA may consider information learned subsequent to authorization of the SIP (21 CFR 251.8(b)). A SIP Sponsor must not make or permit any changes to a SIP without FDA's authorization (21 CFR 251.8(e)). If FDA authorizes changes to a SIP, the Importer must submit a new Pre-Import Request in accordance with 21 CFR 251.5 (21 CFR 251.8(d)).

FDA may suspend or revoke a SIP, in whole or in part, including with respect to one or more drugs in the SIP, at any time, under any circumstances set forth in the FD&C Act and FDA's regulations, including circumstances in FDA's discretion (21 CFR 251.7, and 251.18). An eligible prescription drug cannot be shipped into the United States under section 804 and FDA's regulations, and is subject to refusal of admission into the United States, if FDA has suspended the SIP or revoked its authorization.

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.

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 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,

Sandi L. Verbois -S

Digitally signed by Sandi L. Verbois -S
Date: 2024.01.05 07:41:16 -05'00'

S. Leigh Verbois, PhD
Director
Office of Drug Security, Integrity & Response
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