



November 16, 2022

Lori A. Shibinette, Commissioner
New Hampshire Department of Health and Human Services
129 Pleasant Street
Concord, NH 03301-3857

Re: State of New Hampshire Department of Health and Human Services Section 804
Importation Program Proposal

Dear Commissioner Shibinette:

This letter responds to the Section 804 Importation Program (SIP) proposal that was submitted by the New Hampshire Department of Health and Human Services to FDA on August 30, 2021. Reference is also made to FDA's request for information letter sent to the New Hampshire Department of Health and Human Services on December 14, 2021.

As described in the December 2021 request for information letter, FDA will work with States, such as New Hampshire, and Indian Tribes that propose to develop a SIP under section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the final rule on Importation of Prescription Drugs (see 85 FR 62094; 21 CFR part 251). To assist you with this process, in the December 2021 letter FDA identified information that was not provided in your submission but is required by the final rule. In particular, FDA stated that if a Foreign Seller is not identified within 6 months of the initial submission date of a SIP proposal, which was February 28, 2022 for this submission, the proposal may be denied (21 CFR 251.4(a)). The New Hampshire Department of Health and Human Services has not identified a Foreign Seller, or provided any other requested information. Therefore, FDA is denying New Hampshire's SIP proposal that was submitted on August 30, 2021.

You may submit a new SIP proposal at any time. If you submit a new SIP proposal, please refer to our previous request for additional information for the needed elements. Please submit any questions or a SIP proposal for agency review to SIPDrugImportsandRFP@fda.hhs.gov.

Sincerely,

S. Leigh Verbois, PhD
Director
Office of Drug Security, Integrity & Response
Office of Compliance
Center for Drug Evaluation and Research