



RON DESANTIS
GOVERNOR

JASON WEIDA
SECRETARY

October 20, 2023

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

Re: Florida Agency for Health Care Administration Section 804 Importation Program Proposal

Dear Director Verbois,

The State of Florida and the Florida Agency for Health Care Administration (Agency) respectfully submit this response to the U.S. Food and Drug Administration (FDA)'s August 14, 2023, Request for Information (RFI). Additionally, the Agency appreciates the FDA taking the time to hold conference calls on September 14th and 29th to address questions. Based on those conversations and the written material provided by the FDA, including new label requirements pertaining to dosages received on October 16th, the Agency has revised its Section 804 Importation Program (SIP) proposal in a manner compliant with federal and state statutes that also meets the requirements of Title 21 Code of Federal Regulation § 251.

Enclosed with this letter, the Agency has included attachments consisting of the State of Florida's amended SIP Proposal. This content includes updated policies and procedures from the Importer and Foreign Seller, a revised cost analysis, and new proposed labels as well as other information specified in the RFI.

The Agency remains committed to providing a safe and cost-effective importation program that can support Floridians, lower prescription drug prices, and yield cost savings that can be used to expand health care services. We await your feedback and eagerly look forward to making this proposal a reality.

Sincerely,

Jason Weida
Secretary
Florida Agency for Health Care
Administration

Melanie S. Griffin
Secretary
Florida Department of Business and
Professional Regulation

