

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

Case No. 8:22-cv-1981-TPB-JSS

STATE OF FLORIDA, et al.,

Plaintiffs,

v.

FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

PLAINTIFFS' STATUS REPORT FOR APA CLAIMS

Plaintiffs respectfully submit this status report regarding Florida's SIP Proposal, pursuant to which the State would save over \$100 million annually by importing lower-cost prescription drugs from Canada. The Court has stayed Plaintiffs' APA claims challenging Defendants' delay in adjudicating the SIP Proposal, which has now been pending for over 1,000 days.

As Plaintiffs noted in a prior status report, *see* ECF No. 87, the FDA sent a request for information in August 2023 that included new additional requirements, including that any State seeking to import prescription drugs pursuant to a SIP proposal must have a warehouse within 30 miles of Detroit, Michigan.

Since then, Plaintiffs have met several times with FDA officials, which often led to more requests and requirements. As recently as October 16, 2023,

for example, the FDA sent a PDF with new requirements for labeling imported drugs.

Despite this, Plaintiffs were able to submit an amended SIP Proposal to the FDA on Friday October 20, 2023. *See Attached Cover Letter*. Given the delay while Plaintiffs had to compile materials to address the changing requirements, Plaintiffs understand the FDA is unlikely to be able to issue a decision by their previously stated date of October 31, 2023.

The parties are currently discussing a proposal that would ask the Court to keep the APA claims stayed for a brief period so the FDA can review Florida's amended SIP Proposal, at which point Plaintiffs are confident the FDA will approve the Proposal.

Dated: October 23, 2023

Respectfully submitted,

/s/ R. Trent McCotter
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CERTIFICATE OF SERVICE

I hereby certify that on October 23, 2023, I filed the foregoing via the Court's CM/ECF system, which will serve all counsel.

/s/ R. Trent McCotter
R. TRENT MCCOTTER



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

