

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