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

State of Florida, *et al.*,

Plaintiffs,

v.

Food and Drug Administration, *et al.*,

Defendants.

Case No. 8:22-cv-01981-TPB-JSS

Defendants' Second Supplemental Status Report for the APA Claim

As Defendants previously informed the Court, on August 14, 2023, FDA requested that Florida provide certain critical information missing from its Section 804 Importation Program ("SIP") proposal. *See* ECF No. 85. As long as Florida provided the missing information, or declined to provide any further materials, by August 28, 2023, the date noted in the August 14th request, FDA still anticipated issuing a decision on the proposal by October 31, 2023. *Id.* at 2. Defendants further promised to "apprise the Court of any subsequent, relevant developments regarding the decision-making timeline for Florida's SIP proposal." *Id.* at 2–3. Such developments have occurred.

On August 28, 2023, Florida did not provide the missing information but instead sought a meeting with FDA to clarify certain aspects of the agency's

request. Ex. A. On August 30, FDA scheduled a meeting with Florida, which was held on September 14. During that meeting, Florida requested another meeting with FDA to discuss additional questions raised by the State on September 13. *Id*. The second meeting occurred on September 29. At that meeting, Florida indicated it intended to submit an amended SIP proposal within approximately 30 days, *i.e.,* October 29. *Id.* FDA has not yet received Florida's amendment.

Due to Florida's forthcoming revisions to its SIP proposal, FDA no longer anticipates issuing a decision by October 31. Once FDA receives Florida's submission, the agency will immediately conduct a thorough review.

If Florida submits information that adequately addresses the issues FDA identified in its August 14, 2023 request for information, FDA anticipates that it will be able to render a decision on Florida's SIP proposal within 60 days after receiving the new information. During this review, ODSIR will follow a similar process as it did in reviewing Florida's previous amendments. *See* ECF No. 78-1 Verbois Declaration ¶¶ 10-11. Once FDA receives Florida's submission, FDA will inform the Court of its receipt and of any subsequent, relevant developments regarding the decision-making timeline for Florida's SIP proposal.

October 20, 2023

Respectfully submitted,

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