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,

OF COUNSEL:

SAMUEL R. BAGENSTOS
General Counsel
U.S. Department of Health and Human Services

MARK RAZA
Chief Counsel

WENDY VICENTE
Deputy Chief Counsel, Litigation

SARAH ROSENBERG
Assistant Chief Counsel

WILLIAM THANHAUSER
Associate Chief Counsel
Office of the Chief Counsel
U.S. Food and Drug Administration
10903 New Hampshire Ave.
White Oak 31
Silver Spring, MD 20993-0002

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

JAMES W. HARLOW
Acting Assistant Director
Consumer Protection Branch

/s/ Kimberly R. Stephens
KIMBERLY R. STEPHENS
GABRIEL I. SCHONFELD
Trial Attorneys
Consumer Protection Branch
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386
(202) 505-0033 (Stephens)
(202) 353-1531 (Schonfeld)
Kimberly.R.Stephens@usdoj.gov
Gabriel.I.Schonfeld@usdoj.gov

MARCIA BERMAN
Assistant Director
Federal Programs Branch

OLIVIA HUSSEY SCOTT
Senior Counsel
Federal Programs Branch
Civil Division
U.S. Department of Justice
1100 L Street, N.W., Room 11115
Washington, D.C. 20005
Telephone: (202) 616-8491
Fax: (202) 616-8470
Email: Olivia.Hussey.Scott@usdoj.gov

Exhibit A

U.S. FOOD & DRUG ADMINISTRATION

September 30, 2023

Jason Weida, Secretary
Florida Agency for Health Care Administration
2727 Mahan Drive, Mailstop 1
Tallahassee, FL 32308

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

Dear Secretary Weida,

Thank you for the Florida Agency for Health Care Administration's (AHCA's) attendance at the September 29, 2023 meeting to discuss Florida's Section 804 Importation Program (SIP) proposal. As planned, FDA answered Florida's ten additional questions from its September 13, 2023 correspondence. Formal meeting minutes will be issued at a later date.

As stated at the September 29, 2023 meeting, the August 14 RFI FDA issued to Florida contained all the concerns FDA had identified during its review of Florida's SIP proposal as of April 21, 2023. As the review of Florida's SIP proposal moves forward and the state provides new information, FDA may identify additional issues based on that new information (for example, if the information provided is unclear or inadequate). FDA's goal is to resolve any such issues with Florida as quickly as possible. FDA sends this letter to reassure the state that FDA has been acting expeditiously to issue a decision on the current proposal by taking the following actions:

- Immediately following Florida's April 21, 2023 amendments to its SIP proposal, FDA began re-review of Florida's proposal.
- Upon identifying deficiencies in Florida's April 2023 submission, FDA issued the August 14, 2023 RFI.
    - The RFI identified a number of concerns related to drug supply chain security, cost savings, labeling, and other areas of the SIP proposal.
    - The RFI requested that Florida provide additional or clarifying information by August 28, 2023.
- On the evening of August 28, Florida responded to the August 14, 2023 RFI requesting clarifications on points in the RFI as well as a meeting with FDA. Florida did not provide new information in response to the RFI.
- On August 30, 2023, FDA scheduled a meeting with Florida for September 14, 2023. At the same time, FDA asked that Florida send any additional questions by September 7, 2023, so that FDA would have time to prepare responses.
- On the afternoon of September 13, 2023, Florida sent a list of ten additional questions to FDA regarding the August 14 RFI and SIP program.
- At the September 14, 2023 meeting, FDA answered several of Florida's requests for clarification from its August 28 letter. FDA noted that it would respond as

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

soon as possible to Florida's additional ten questions, but it was unable to do so at the September 14 meeting because it had received the questions the day before.

- At the close of the meeting, Florida requested an additional meeting to discuss its additional ten questions.
- On September 14, 2023, FDA reached out to Florida and scheduled another meeting for September 29, 2023.
- On September 22, 2023, FDA asked a clarifying question about information Florida sought regarding a disclosure issue that was related to one of Florida's ten questions, so FDA could be best prepared to answer the question at the September 29 meeting.
- On September 29, 2023, FDA met with Florida, and FDA provided responses to Florida's ten questions submitted on September 13, 2023. At the meeting, Florida indicated that it would send FDA an additional question in writing regarding the August 14 RFI. FDA asked for Florida to provide an estimated timeline for its responses to the August 14 RFI. Florida indicated that it would aim to submit responses within approximately 30 days.

As discussed during the meeting, once Florida responds to the August 14 RFI with the information requested, FDA will immediately resume conducting a thorough review of the revised proposal, including that new information. Once Florida has sufficiently addressed all information requested, FDA anticipates that it will be able to render a prompt decision regarding Florida's SIP proposal.

Please submit any questions, requests to meet, or revisions to Florida's SIP proposal for agency review to SIPDrugImportsandRFP@fda.hhs.gov.

Sincerely,

Sandi L. Verbois -S Digitally signed by Sandi L. Verbois -S
Date: 2023.09.30 10:33:14 -04'00'

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