

Congress of the United States

Washington, DC 20510

November 2, 2022

The Honorable Robert Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

We write regarding the continued delay in approving the State of Florida's Agency for Health Care Administration (AHCA) Section 804 Importation Program (SIP) proposal for the Importation of Prescription Drugs from Canada. It has been more than 700 days since AHCA submitted their proposal, yet, the state has received no update or timeline from the FDA on the latest SIP proposal. As such, we ask for an update on Florida's SIP application and that the FDA work with Governor DeSantis to expeditiously approve Florida's proposal to safely import certain prescription drugs from Canada.

The Biden Administration, which wants to lower drug costs for Americans, especially its older citizens, continues to delay the approval of Florida's proposal intending to do exactly that. Since AHCA first submitted its SIP proposal in November 2020, AHCA has worked diligently to answer the FDA's questions and make suitable adjustments. Florida is the first state to submit a SIP proposal to the FDA and other states have followed suit. It is our understanding that the FDA was previously reviewing Florida's SIP proposal and even submitted two requests for information, to which AHCA promptly responded. However, the FDA has failed to provide a substantive update since November 2021. AHCA officials have attempted to reach out to the FDA for months but have received no additional requests for information or a timeline since a meeting in May 2022. This situation is particularly frustrating as information has come to light that the FDA is actively working with other states on developing their SIP proposals while Florida's program remains stalled.

If the Biden Administration is serious about lowering the cost of prescription drugs, then the FDA must do its job and follow through with the State of Florida's drug importation plan. We look forward to your prompt response and action on this important matter.

Sincerely,



Marco Rubio
U.S. Senator



Mario Diaz-Balart
Member of Congress



John H. Rutherford
Member of Congress



Gus M. Bilirakis
Member of Congress



Neal P. Dunn, M.D.
Member of Congress



Brian Mast
Member of Congress

Cc: Xavier Becerra, Secretary, U.S. Department of Health and Human Services