RAPHAEL WARNOCK
GEORGIA

United States Senate
WASHINGTON, DC 20510

June 28, 2022

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

Dear Commissioner Califf,

I write today to express my concern with the Food and Drug Administration (FDA)'s handling of the infant formula shortage. The FDA must respond to this crisis with urgency and targeted relief – the lives of Georgia families are depending on it.

Parents across the state of Georgia are overwhelmed with the stress of trying to feed their babies. There is no alternative to formula for families who cannot or choose not to breastfeed. Additionally, many young children who have allergies or medical needs rely on special formula. This has been an extremely challenging few months for Georgia families.

I am glad that Congress could come together to pass the *Access to Baby Formula Act*, which I helped introduce, so that families who rely on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) have more flexibility in accessing formula during this crisis. I have also encouraged the Administration and manufacturers to work together to increase formula production and prevent future supply chain disruptions.

That said, it is clear that there are serious systemic issues at the FDA, as you have acknowledged. The first consumer complaints about the bacterial contamination at the Abbott Nutrition ("Abbott") manufacturing facility were reported in September 2021. However, the FDA did not announce its investigation into the contamination until February 17, 2022.[1] It is alarming that it took nearly six months for the FDA to act.

The FDA should have been prepared at the onset of these complaints for the potential consequences. Abbott is only one of a few formula manufacturers in the United States, and Abbott alone accounts for 48 percent of the nation's formula.[2] Federal responsibility for the well-being of our children is of the utmost importance, and it is simply unacceptable that the FDA was not prepared to respond to this crisis.

[1] Congressional Research Service, May 21, 2022.
[2] Julie Creswell and Madeleine Ngo, "Baby Formula Shortage Has an Aggravating Factor: Few Producers," *New York Times*, May 20, 2022.

To ensure that the FDA is equipped to respond to crises in the future, I respectfully ask you to submit answers in writing to the following questions by July 31, 2022:

1. What is the FDA currently doing to assist companies in replenishing the nation's baby formula supply?
2. Does the FDA have a target date for when baby formula supplies will return to pre-shortage levels? If so, when is it? How specifically is the FDA working with baby formula companies to help ensure this target date is met?
3. How will you address systemic failures in chain of command when handling whistleblower complaints?
4. What is your plan for responding to contamination and oversight issues at manufacturing facilities?
5. Will the FDA commit to informing Congress of its plans to develop a thorough process for responding to these crises?
6. What kind of support does the FDA require so that formula shortages do not occur in the future?
7. How can the FDA work to improve its oversight of manufacturers, like Abbott, so that conditions do not reach crisis-levels before being addressed?

I understand that this issue is complex, especially due to existing supply chain issues, and I appreciate your work to address the shortages as expeditiously as possible. However, Georgia families are struggling now, and we owe it to them to do all that we can to get formula back on the shelves and to ensure that this never happens again. Thank you again for your attention to this matter.

Sincerely,

Reverend Raphael Warnock
U.S. Senator