ROGER W. MARSHALL
KANSAS

COMMITTEES:
AGRICULTURE, NUTRITION, AND FORESTRY
ENERGY AND NATURAL RESOURCES
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SMALL BUSINESS AND ENTREPRENEURSHIP

United States Senate

September 13, 2022

The Honorable Thomas Vilsack
Secretary
U.S. Department of Agriculture
1400 Independence Ave. SW
Washington, DC 20250

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Sameera Fazili
Deputy Director
National Economic Council
Eisenhower Executive Office Building
1650 17th St NW,
Washington, DC 20500

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

Dear Secretary Vilsack, Secretary Becerra, Commissioner Califf, and Director Fazili,

I write today regarding the ongoing baby formula crisis still facing American families across the country and urge you to reconsider recent actions from the Food and Drug Administration (FDA) that further contribute to the shortage of available formula. The FDA's track record over the last several months raises serious questions about the Biden Administration's handling of this crisis. The slow approval process, approval of inexperienced manufacturers, reliance on Chinese-owned companies, and recent round of application deferrals all send the wrong signal to American families who still struggle to find formula. I urge you to prioritize your work to fix this dire problem for American families and make decisions that will put formula back on the shelves as quickly as possible. Formula shortages are still impacting American families.

It has been nearly seven months since one of the largest infant formula manufacturers in the nation was shut down following concerns raised by the FDA and Centers for Disease Control and Prevention (CDC). This directly resulted in an unprecedented shortage of infant formula supply on grocery store shelves, and left parents scrambling to find healthy and affordable formula for their infants. In May, as the crisis continued, retailers began limiting purchasing access to formula, which restricted the amount of formula a parent could take home at one time. Even now, after multiple measures taken by the Administration and Congress, parents live in fear of not being able to find infant formula on shelves, as the full supply still has yet to rebound. At the end of July, stocking rates for infant formula in stores on the national scale were at 80 percent, and worse yet, around 60 percent in my home state of Kansas and neighboring Colorado, still leaving families in crisis nearly half a year later.

Several weeks ago, media reports indicated that the FDA deferred multiple requests from well-respected formula manufacturers to enter into the market. These deferrals are by all accounts de facto rejections and run counter to FDA commitments to allow imported baby formula under a temporary program with appropriate health and safety standards. This shortage will not be fixed by allowing the FDA to be held captive to special interest groups and protectionist lobbying efforts more concerned about preventing new competition in the baby formula market than the health of American children. Stocking rates could return to pre-crisis levels if the FDA reconsidered their short-term approvals for ready to ship

formula and specialty formula. Leadership on these issues is needed now more than ever to give American families the peace of mind they deserve.

In an effort to understand the recent decisions by the FDA, I respectfully request responses to the following questions by September 23, 2022:

1. Was the USDA consulted ahead of the FDA's decision to issue short-term application deferrals? If so, when did this occur and what was USDA's involvement?
2. Was HHS consulted or informed ahead of the FDA's decision to issue short-term application deferrals?
3. Do you believe there is an ongoing infant formula crisis?
4. Has the White House offered input on the approval or disapproval of specific companies going through the FDA's approval process? If so, when did this occur and which companies were referenced?
5. Why is the FDA seemingly approving base powder that will be mixed within the U.S.—a step which slows down the process of putting formula on the shelves—rather than approving formula that is ready to ship?
6. While the FDA publicly lists the approved applications, company names, origin of product and capacity, many significant details are missing. Please share the committed quantities of formula for each company as well as their lifetime record of formula production, amounts produced by year for the last 10 years, the location of each company's ownership, and length of time each company has been operational for all applications approved under the short-term emergency approval process
7. When was the last time you two spoke or met regarding the FDA's approval process?
8. Is the White House consulting the FDA on the need for approval of additional applicants?

Thank you in advance for your responses. I ask that you respond no later than September 23, 2022.

Sincerely,

Roger Marshall, M.D.
United States Senator