

United States Senate

WASHINGTON, DC 20510

May 16, 2022

Commissioner Robert Califf
US Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Califf:

We write today with great concern regarding the infant formula shortage that has impacted families with young children across the United States, including Nevadans. If this shortage is not resolved quickly, families will have few options for ensuring their young children, especially infants, get the critical nutrition they need.

Earlier this month, 43 percent of formula was out of stock at retailers nationwide, compared with 31 percent about a month ago.¹ But the shortage has hit some areas worse than others: Las Vegas is facing an out-of-stock rate of over 52 percent, the highest of any US metro area.²

We recognize the administration's efforts thus far to address the current shortage³, including by working to increase domestic supply, and expediting imports of formula, but these actions should have happened sooner. We also recognize the importance of actions taken by the US Food and Drug Administration (FDA) in response to contaminated formula products, which were necessary to protect the health and lives of infants, and we urge additional actions to be taken to ensure that production of essential products—especially specialized infant formula for young children with specific nutritional needs—is addressed simultaneously to prevent shortages.

US consumers have experienced significant supply chain disruption since the onset of the COVID-19 pandemic, and industries continue to manage existing and emerging logistical hurdles. Disruptions ranging from workforce challenges to materials shortages hamper businesses with domestic and international operations. Through immediate investments in the American Rescue Plan Act that have helped bring Americans back to work, and long-term investments in the bipartisan Infrastructure Investment and Jobs Act that will help shore up domestic capacity by modernizing our transit and supply lines, Congress has helped to avert catastrophic losses and shortages. But supply chain challenges remain. These issues will not be resolved overnight, but rather require long-term coordinated efforts of both government and industry.

For example, throughout the pandemic, the federal government has used emergency powers to compel manufacturers of critical drugs and medical devices to report anticipated or actual supply

¹ [Bloomberg](#)

² [Bloomberg](#)

³ <https://www.hhs.gov/formula>

chain disruptions that could impede access to essential services and therapies. Impacted manufacturers have been encouraged to keep in close contact with the FDA regarding changes in the production of certain products to help prevent or mitigate shortages during the public health emergency.

While this level of supply chain transparency may be unnecessary in the context of the overall food supply where a variety of substitutions are available, formula is a uniquely important product that families rely on for infant nutrition. Specialty infant formula in particular, which supports babies who often cannot metabolize other food sources, is essential to support the health of children nationwide.

In order to better understand the drivers of this shortage, the steps FDA is taking to combat it, and how Congress can help to prevent similar disruptions in the future, we respectfully request answers to the following questions by June 6, 2022:

1. Does the FDA have the tools and authorities necessary to predict shortages based on supply chain disruptions in infant formula and essential nutritional supplements that do not have easily accessible substitutes?
2. For specialty formula in particular, what additional data would be necessary for FDA to collect in order to better predict and prevent such shortages?
3. What tools does FDA have to address such shortages when they become apparent, and how is the agency employing those authorities under the current circumstances? How quickly can these actions be taken?
4. In the context of the current formula shortage, how is FDA working in concert with other agencies to utilize other authorities not delegated to FDA, including trade authorities and those under the Defense Production Act?
5. As the administration continues to implement recommendations from the White House Supply Chain Task Force on building long-term supply chain resilience, what actions will help to alleviate supply chain-related challenges specific to infant formula shortages?

We appreciate the action that FDA and other agencies have undertaken to mitigate the impacts of this shortage but must emphasize that many parents and caregivers of infants in Nevada and across the country are feeling an extreme amount of distress because of the current situation. We urge clear communication to the public regarding updates on shortages, including cross-agency collaboration to provide regular updates on availability of formula products, safety of alternatives, and where to find up-to-date information. We look forward to working with you to ensure that the administration has the tools it needs to protect access to infant formula now and in the future.

Sincerely,



Catherine Cortez Masto
United States Senator



Jacky Rosen
United States Senator