

Congress of the United States
Washington, DC 20510

May 11, 2022

The Honorable Joseph R. Biden, Jr.
President of the United States
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

The Honorable Robert M. Califf, M.D., MACC
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

President Biden and Dr. Califf:

We write to you about concerns over the nationwide shortage of baby formula and your inaction to address this ongoing crisis. Parents are understandably frustrated and scared by this shortage. In fact, the formula shortage has reached crisis levels in recent weeks. The share of baby formula “out of stock across the U.S. hit 40 percent on April 24” and a “total of 26 states have out of stock rates of 40 to 50 percent.”¹ Notably, CVS, Walgreens, and Target are among the stores putting limits on how much formula customers can buy at one time.²

According to Datasembly, baby formula shortages were at 23 percent in January 2022 “and have continued to worsen, showing [out of stock] levels now at 31% as of April 2022.”³ Further, Ben Reich, the CEO of Datasembly, said a combination of “inflation, supply chain shortages, and product recalls have brought an unprecedented amount of volatility for baby formula” and that he expects “to continue to see the baby formula category being dramatically affected by these conditions.”⁴ Mr. Reich warns that baby formula “will continue to demonstrate higher than average out-of-stock levels.”⁵

¹ Rob Wile, *40 percent of America’s baby formula supplies are out of stock*, NBC News (May 9, 2022), available at <https://www.cnbc.com/2022/05/09/40-percent-of-americas-baby-formula-supplies-are-out-of-stock.html>

² Rachel Paula Abrahamson and Elise Sole, *Everything you need to know about the baby formula shortage*, Today (Feb. 9, 2022), available at https://www.today.com/parents/parents/everything-need-know-baby-formula-shortage-rcna15613?icid=canonical_related

³ Business Wire, *Datasembly Data Reveals 31% Out-Of-Stock Rate in April 2022 for Baby Formula; Up 11% Compared to November 2021*, (Apr. 13, 2022), available at <https://www.businesswire.com/news/home/20220413005974/en/Datasembly%E2%80%99s-Data-Reveals-31-Out-of-Stock-Rate-in-April-2022-for-Baby-Formula-Up-11-Compared-to-November-2021>

⁴ *Id.*

⁵ *Id.*

Parents across the country are struggling to keep up with this nationwide shortage of baby formula, a problem worsened by a recent recall by Abbott Nutrition, a manufacturer of infant formula. The recall came after at least four babies were hospitalized with bacterial infections and two died after consuming powdered infant formula produced in its Sturgis, Michigan facility, according to the Food and Drug Administration (FDA).⁶ The shortage is also a financial burden for families already dealing with historic inflation rates that your administration has done little to address. The office of the U.S. Surgeon General states that families typically spend \$1,200 to \$1,500 on infant formula in the first year.⁷

We also note that the FDA released an April 29, 2022, update on its non-objection to Abbott Nutrition releasing specialty and metabolic formulas produced at a Michigan facility on a case-by-case basis. The update stated:

[T]he FDA has informed Abbott Nutrition that the agency has no objection to the company immediately releasing product to individuals needing urgent, life-sustaining supplies of the specialty and metabolic formulas listed below on a case-by-case basis. The FDA is concerned that the risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions and in some cases pose life-threatening risks for infants and individuals who rely on these products. In these circumstances, the benefit of allowing parents, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection.

Baby formula shortages are an urgent problem that must be addressed immediately. Unfortunately, the administration has done little to increase the supply of infant formula. House Republicans call on the administration to do more to help parents across this country. This issue is a matter of life and death, and it is time this administration treats it with the appropriate urgency it deserves. Accordingly, to assist us in our oversight, please provide the following by May 18, 2022:

1. Please explain the meaning of FDA's April 29, 2022, update, and if FDA expects its non-objection to help mitigate the supply shortage? If so, how is it expected to mitigate the shortage?
2. What data does the FDA have on the supply of infant formula?
3. What is FDA's understanding of what is causing the shortage of infant formula?
4. How did FDA account for infant formula supply impacts from the recalls?

⁶ FDA, *Company Announcement: Abbott Voluntarily Expands Recall of Powder Formulas Manufactured at One Plant*, (Feb. 28, 2022), available at <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/abbott-voluntarily-expands-recall-powder-formulas-manufactured-one-plant#:~:text=02.17.,any%20metabolic%20deficiency%20nutrition%20formulas>.

⁷ Office of Surgeon General, *Breastfeeding: Surgeon General's Call to Action Fact Sheet*, available at <https://www.hhs.gov/surgeongeneral/reports-and-publications/breastfeeding/factsheet/index.html>

5. What action is FDA taking to track the shortage?
6. What are FDA's plans to help address the shortage?
7. What action is FDA taking related to the resolution of any issues resulting in the temporary closure of the facility in Sturgis, MI?
8. What outreach has the Administration performed to hospital pediatric units to determine if they have enough baby and specialty formula in reserve for emergency situations?
9. What data is available regarding whether non-infants who rely on specialty formula are having any adverse reactions to currently available formula?
10. What formula production facilities are available beyond U.S. borders, and to what extent have these facilities been impacted by transit bottlenecks due to COVID lockdowns?

Please also provide a briefing for the Minority staff of the Energy and Commerce Committee after sending your written response. If you have any questions, please contact the Minority Committee staff at (202) 225-3641. Thank you for your attention to this request.

Sincerely,