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 failure to meaningfully 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] Additionally, there is concern over how this may impact parents participating in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), who rely on the program's supply of baby formula for their infant's nutritional needs.

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

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[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

affected by these conditions."[4] Mr. Reich warns that baby formula "will continue to demonstrate higher than average out-of-stock levels."[5]

Parents across the country are struggling to keep up with this nationwide shortage of baby formula. This problem worsened in February 2022 when, Abbott Nutrition, a manufacturer of infant formula, voluntarily recalled formula produced in its Sturgis, Michigan facility following reports of infant hospitalizations and death. The facility was subsequently shut down pending an investigation by the FDA and enhanced testing. Since then, a link has not been established between the formula produced at the facility and the sickened infants.

On April 29, 2022, the FDA announced that it did not object to Abbott Nutrition releasing specialty and metabolic formulas produced at the Sturgis facility on a case-by-case basis. Yet, the FDA has still not cleared the facility to resume the vast majority of its infant formula production. The prolonged shutdown of the Sturgis facility without any public backup plan by the administration has greatly exacerbated the current shortage.

Baby formula shortages are an urgent problem that must be addressed immediately. This new problem is compounded by the historic inflation caused by the Biden administration that is already burdening families. 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.[6]

Just yesterday, the FDA announced a number of steps it will take in an attempt to "improve supply of infant and specialty formula products."[7] However, this announcement comes far too late, as parents struggle to find formula for their babies. 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? Please explain how long the additional testing is expected to take and what the timeline is for reopening Abbott's Sturgis, Michigan facility.

2. With respect to the steps FDA recently announced, please answer the following:

    a. How will these steps meaningfully increase supply?

    b. When does the agency expect to see a supply increase, particularly in states experiencing significant shortages?

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[4] *Id*.
[5] *Id*.
[6] 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
[7] FDA, *FDA Takes Important Steps to Improve Supply of Infant and Specialty Formula Products*, (May 10, 2022), *available at* https://content.govdelivery.com/accounts/USFDA/bulletins/317391e

c. Please identify what and the number of specific "reviews" and "certificates" in the regulatory process you are "expediting" to increase supply.

d. Please explain how you will exercise discretion on "minor labeling issues" to increase supply?

e. Are there any additional steps the FDA is considering?

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?

5. What action is FDA taking to track the shortage?

6. What action is FDA taking related to the resolution of any issues resulting in the temporary closure of the facility in Sturgis, MI?

7. 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?

8. What data is available regarding whether non-infants who rely on specialty formula are having any adverse reactions to currently available formula?

9. 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,

Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce

Brett Guthrie
Republican Leader
Subcommittee on Health
Committee on Energy and Commerce

H. Morgan Griffith
Republican Leader
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

Fred Upton
Member of Congress

Tim Walberg
Member of Congress

Michael C. Burgess, M.D.
Member of Congress

Steve Scalise
Member of Congress

Robert E. Latta
Member of Congress

David B. McKinley
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Gus M. Bilirakis
Member of Congress

Bill Johnson
Member of Congress

Billy Long
Member of Congress

Larry Bucshon, M.D.
Member of Congress

Markwayne Mullin
Member of Congress

Richard Hudson
Member of Congress

Earl L. "Buddy" Carter
Member of Congress

Jeff Duncan
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Gary J. Palmer
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Neal P. Dunn, M.D.
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John R. Curtis
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Debbie Lesko
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John Joyce, M.D.
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Kelly Armstrong
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Frank D. Lucas
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Kevin Brady
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Sam Graves
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Darrell Issa
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Virginia Foxx
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Vern Buchanan
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Doug Lamborn
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Rob Wittman
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Blaine Luetkemeyer
Member of Congress

Tom McClintock
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Glenn "GT" Thompson
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Eric A. "Rick" Crawford
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Mo Brooks
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Bob Gibbs
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