

**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.”<sup>1</sup> Notably, CVS, Walgreens, and Target are among the stores putting limits on how much formula customers can buy at one time.<sup>2</sup> 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.”<sup>3</sup> 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

---

<sup>1</sup> 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>

<sup>2</sup> 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](https://www.today.com/parents/parents/everything-need-know-baby-formula-shortage-rcna15613?icid=canonical_related)

<sup>3</sup> 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.”<sup>4</sup> Mr. Reich warns that baby formula “will continue to demonstrate higher than average out-of-stock levels.”<sup>5</sup>

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.<sup>6</sup>

Just yesterday, the FDA announced a number of steps it will take in an attempt to “improve supply of infant and specialty formula products.”<sup>7</sup> 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?

---

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*


<sup>6</sup> 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>

<sup>7</sup> 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.

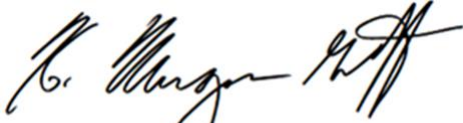
Sincerely,



Cathy McMorris Rodgers  
Republican Leader  
Committee on Energy and Commerce



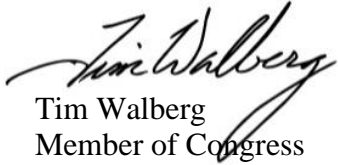
Brett Guthrie  
Republican Leader  
Subcommittee on Health  
Committee on Energy and Commerce



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



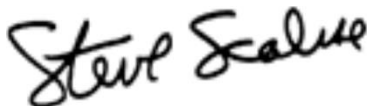
Fred Upton  
Member of Congress



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  
Member of Congress



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



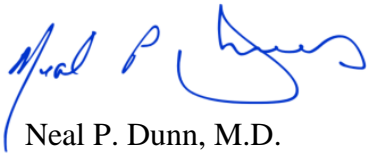
Earl L. "Buddy" Carter  
Member of Congress



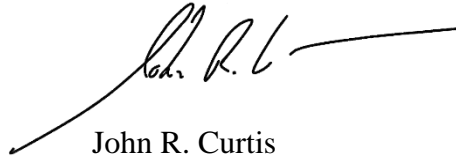
Jeff Duncan  
Member of Congress



Gary J. Palmer  
Member of Congress



Neal P. Dunn, M.D.  
Member of Congress



John R. Curtis  
Member of Congress



Debbie Lesko  
Member of Congress



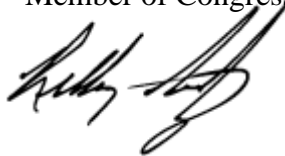
Greg Pence  
Member of Congress



Dan Crenshaw  
Member of Congress



John Joyce, M.D.  
Member of Congress



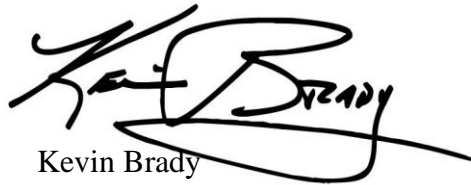
Kelly Armstrong  
Member of Congress



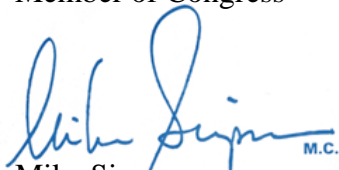
Ken Calvert  
Member of Congress



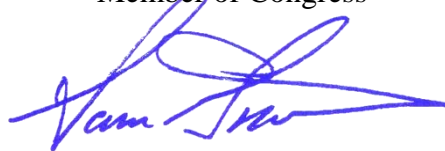
Frank D. Lucas  
Member of Congress



Kevin Brady  
Member of Congress



Mike Simpson  
Member of Congress



Sam Graves  
Member of Congress



Darrell Issa  
Member of Congress



Virginia Foxx  
Member of Congress



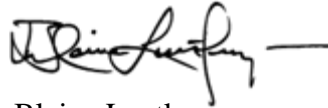
Vern Buchanan  
Member of Congress



Doug Lamborn  
Member of Congress



Rob Wittman  
Member of Congress



Blaine Luetkemeyer  
Member of Congress



Tom McClintock  
Member of Congress



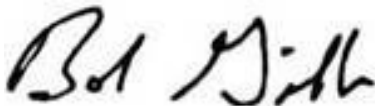
Glenn "GT" Thompson  
Member of Congress



Eric A. "Rick" Crawford  
Member of Congress



Mo Brooks  
Member of Congress



Bob Gibbs  
Member of Congress



Bill Huizenga  
Member of Congress



Steven M. Palazzo  
Member of Congress



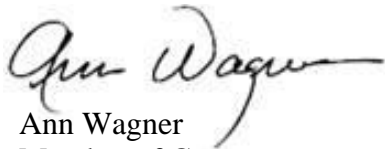
Austin Scott  
Member of Congress



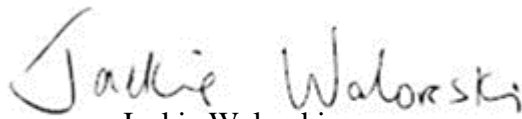
Andy Barr  
Member of Congress



Doug LaMalfa  
Member of Congress



Ann Wagner  
Member of Congress



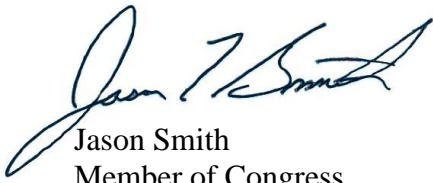
Jackie Walorski  
Member of Congress



Brad R. Wenstrup, D.P.M.  
Member of Congress



Roger Williams  
Member of Congress



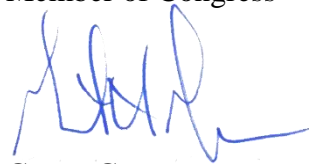
Jason Smith  
Member of Congress



Rick Allen  
Member of Congress



Tom Emmer  
Member of Congress



Garret Graves  
Member of Congress



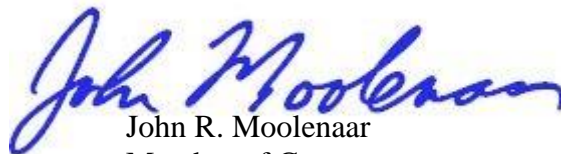
Glenn Grothman  
Member of Congress



John Katko  
Member of Congress



Barry Loudermilk  
Member of Congress



John R. Moolenaar  
Member of Congress



Dan Newhouse  
Member of Congress



Elise Stefanik  
Member of Congress



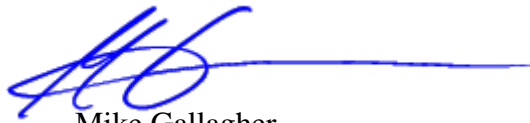
David G. Valadao  
Member of Congress



Drew Ferguson  
Member of Congress



Brian Fitzpatrick  
Member of Congress



Mike Gallagher  
Member of Congress



Clay Higgins  
Member of Congress



John H. Rutherford  
Member of Congress



Ralph Norman  
Member of Congress



Ben Cline  
Member of Congress



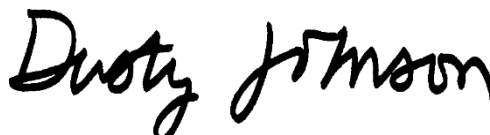
Anthony Gonzalez  
Member of Congress



Mark E. Green, M.D.  
Member of Congress



Michael Guest  
Member of Congress

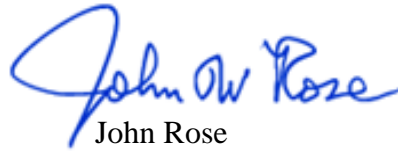


Dusty Johnson  
Member of Congress





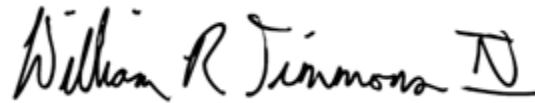
Guy Reschenthaler  
Member of Congress



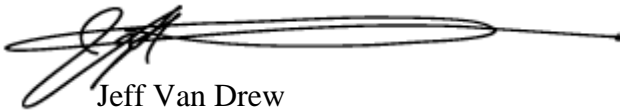
John Rose  
Member of Congress



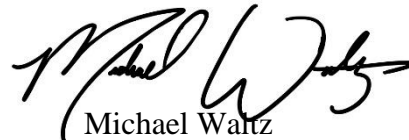
Pete Stauber  
Member of Congress



William R. Timmons, IV  
Member of Congress



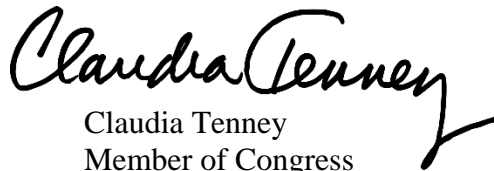
Jeff Van Drew  
Member of Congress



Michael Waltz  
Member of Congress



Gregory F. Murphy, M.D.  
Member of Congress



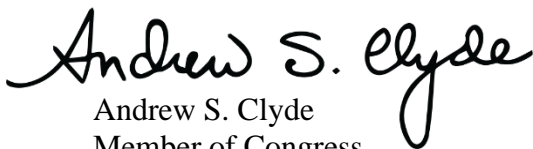
Claudia Tenney  
Member of Congress



Cliff Bentz  
Member of Congress



Kat Cammack  
Member of Congress



Andrew S. Clyde  
Member of Congress



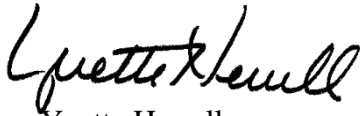
Michelle Fischbach  
Member of Congress



Bob Good  
Member of Congress



Diana Harshbarger  
Member of Congress



Yvette Herrell  
Member of Congress



Jake LaTurner  
Member of Congress



Nancy Mace  
Member of Congress



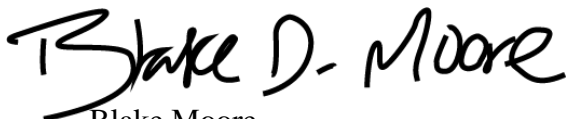
Tracey Mann  
Member of Congress



Peter Meijer  
Member of Congress



Mariannette J. Miller-Meeks, M.D.  
Member of Congress



Blake Moore  
Member of Congress



August Pfluger  
Member of Congress



Maria Elvira Salazar  
Member of Congress



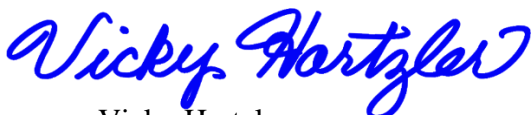
Beth Van Duyne  
Member of Congress



Carol D. Miller  
Member of Congress



Daniel Webster  
Member of Congress



Vicky Hartzler  
Member of Congress



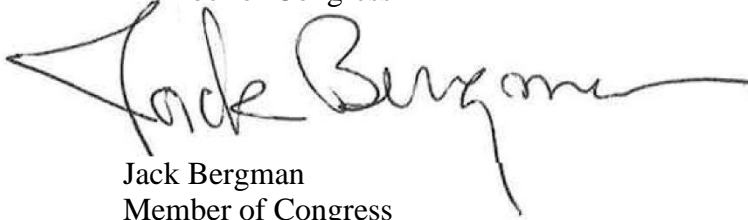
Andrew R. Garbarino  
Member of Congress



Louie Gohmert  
Member of Congress



Mike Garcia  
Member of Congress



Jack Bergman  
Member of Congress



Stephanie Bice  
Member of Congress



Robert B. Aderholt  
Member of Congress



Chris Stewart  
Member of Congress