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 Datasmoby, 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 Datasmoby, 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

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-rena15613?cid=canonical_related
affected by these conditions.” Mr. Reich warns that baby formula “will continue to demonstrate higher than average out-of-stock levels.”

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.

Just yesterday, the FDA announced a number of steps it will take in an attempt to “improve supply of infant and specialty formula products.” 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.
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
Darrell Issa  
Member of Congress

Vern Buchanan  
Member of Congress

Rob Wittman  
Member of Congress

Tom McClintock  
Member of Congress

Eric A. “Rick” Crawford  
Member of Congress

Bob Gibbs  
Member of Congress

Steven M. Palazzo  
Member of Congress

Virginia Foxx  
Member of Congress

Doug Lamborn  
Member of Congress

Blaine Luetkemeyer  
Member of Congress

Glenn “GT” Thompson  
Member of Congress

Mo Brooks  
Member of Congress

Bill Huizenga  
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

David G. Valadao  
Member of Congress

Brian Fitzpatrick  
Member of Congress

Clay Higgins  
Member of Congress

Ralph Norman  
Member of Congress

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Michael Guest  
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Member of Congress

Drew Ferguson  
Member of Congress

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Member of Congress

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Member of Congress

Ben Cline  
Member of Congress

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

Dusty Johnson  
Member of Congress
Guy Reschenthaler
Member of Congress

Pete Stauber
Member of Congress

Jeff Van Drew
Member of Congress

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

Cliff Bentz
Member of Congress

Andrew S. Clyde
Member of Congress

Bob Good
Member of Congress

John Rose
Member of Congress

William R. Timmons, IV
Member of Congress

Michael Waltz
Member of Congress

Claudia Tenney
Member of Congress

Kat Cammack
Member of Congress

Michelle Fischbach
Member of Congress

Diana Harshbarger
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