Congress of the United States Washington, DC 20515

May 10, 2022

The Honorable Dr. Robert M. Califf Commissioner of Food and Drugs U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

Dear Commissioner Califf:

We write today to express great concern with the ongoing shortage of infant formula across the United States. We have heard from constituents about this issue – parents who are unsure how to provide this essential sustenance for their babies and worried about the nutritional impacts of this supply chain shortage. As moms ourselves, we know the stress this is causing in so many households.

This comes at a time when working families are already struggling with smaller paychecks resulting from this Administration's inflationary policies. Wages do not go as far as they did a year ago, inflation has risen over 8.5 percent (the highest rate in over 40 years),² and families are making tough decisions between filling up their gas tanks and filling up their grocery carts. Now, it is no longer even an option to add infant formula to the cart - there is none on the shelf to buy.3

The infant formula shortage is yet another example of how this Administration's supply chain crisis is harming working families. This crisis has now come home to America's kitchen tables. as families do not know how to feed their children. According to your own agency's data, 67 percent of children (2.7 million babies) "rely on infant formula for some portion of their nutrition" by the age of three months. ⁴ This crisis must be addressed.

Make no mistake, the families suffering the most from this infant formula supply chain crisis are some of our most vulnerable. Rural Americans are unable to procure formula entirely in some

and Infant Formula," Nutrients, May 11, 2016, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4882692/#B6-

¹ Bailee Hill, "Baby formula shortage alarms mothers: 'On the verge of a public health crisis'," Fox News, May 9, 2022, https://www.foxnews.com/media/baby-formula-shortage-public-health-crisis-friends.

² Anneken Tappe, "Consumer price inflation hit a new 40-year high in March," CNN, April 12, 2022, https://www.cnn.com/2022/04/12/economy/consumer-price-inflation-march/index.html.

³ Datasembly, "Data Shows Out-of-Stock Impacts of Inflation, Supply Chain Issues, and Recalls as Out-of-Stock Rate in April 2022 hits 31%," April 13, 2022, https://datasembly.com/news/out-of-stock-rate-in-april-2022/. ⁴ Camilia R. Martin, Pei-Ra Ling, and George L. Blackburn, "Review of Infant Feeding: Key Features of Breastmilk

communities. This includes the parents and children we represent in Northeast Iowa⁵ and Upstate New York.⁶ Babies who need specialty formula for medical conditions are suffering. Families that depend on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) are at a loss.

This supply chain crisis-induced infant formula shortage is only worsening. According to a recent CNN report, six states, including Iowa, were sold out of more than half of their infant formula for the week of April 24th, and "26 states are now struggling with supply." This is not an idle concern for the Administration to ignore like it does with its other crises – this is a life-ordeath matter for many families. Roughly 40 percent of the nation's infant formula is out of stock; in the last two weeks alone, the percentage of out-of-stock infant formula has jumped 9 percent.

This has caused panic in communities across the country, as popular stores turn to rationing formula to make their stock last. Parents should never be in a position of not knowing where to procure formula for their babies. Frankly, these empty shelves are unacceptable. Families deserve better.

The families we represent need answers, and they need certainty. As such, we respectfully request answers to the following questions:

- 1. What is the current status of the immediate shortage and when does the U.S. Food and Drug Administration (FDA) anticipate shelves to be restocked of infant formula fully to pre-shortage levels? Please provide a clear timeline for when inventory is expected to return to sufficient levels.
- 2. What steps has the FDA taken to minimize the impact of the immediate shortage?
- 3. What measures should be taken in the long term to minimize supply chain disruptions for an essential product for families?
- 4. To what extent is the FDA communicating directly with states and major retail stockists pertaining to this shortage?

⁵ Kristin Rogers, "Iowa parents scramble to find baby formula amid nationwide shortage," *KCRG*, May 6, 2022, https://www.kcrg.com/2022/05/06/iowa-parents-scramble-find-baby-formula-amid-nationwide-shortage/.

⁶ Katelynn Ulrich, "What's behind baby formula shortage, and when it could end," *Spectrum News 1*, April 29, 2022, https://spectrumlocalnews.com/nys/central-ny/news/2022/04/29/why-there-s-a-baby-formula-shortage--and-when-it-could-end-.

Parija Kavilanz and Ramishah Maruf, "The baby formula supply problem is getting worse," CNN Business, Mary
2022, https://www.cnn.com/2022/05/08/business/baby-formula-shortage/index.html.
Ibid.

⁹ Mike Snyder, "Baby formula shortage worsens: About 40% of popular brands sold out across US," *USA Today*, May 7, 2022, https://www.usatoday.com/story/money/shopping/2022/05/07/baby-formula-shortage-cvs-target-walgreens-limit-sales/9686941002/.

- 5. Is the FDA currently working on plans to collaborate with manufacturers to increase production, imports, general supply, FDA approvals, and nationwide availability of infant formula products?
- 6. What are the FDA's plans to monitor this sort of critical supply moving forward?
- 7. White House Press Secretary Jen Psaki stated on May 9, 2022, that the FDA is taking "a number of steps" to address this infant formula shortage, including prioritizing product lines that are of the greatest need. Can you share what this prioritization involves?
- 8. Is the FDA tracking specific community-based need and intending to prioritize supply to rural Americans and other under-served communities that are currently experiencing the highest shortages?
- 9. Is the FDA planning to rearticulate its 21 FORWARD program to address post-pandemic supply chain crises like this one? If so, please explain how.

Thank you for your prompt attention to this matter.

Sincerely,

Ashley Hinson

Member of Congress

Elise Stefanik

Member of Congress