

May 13, 2022

The Honorable Robert M. Califf, M.D., MACC  
Commissioner  
Food and Drug Administration

The Honorable Alejandro Mayorkas  
Secretary  
Department of Homeland Security

The Honorable Katherine C. Tai  
United States Trade Representative

Dear Commissioner Califf, Secretary Mayorkas and Ambassador Tai:

Supply shortages of infant formula are putting unimaginable burdens on parents.<sup>1</sup> The severe shortage of infant formula appears to be a result of supply chain constraints and the shutdown of a major production facility in Michigan.<sup>2</sup> Families are already facing 40-year high inflation and surging energy costs. These parents should not have to also worry about how to feed their babies. The Food and Drug Administration (FDA), Department of Homeland Security (DHS) and United States Trade Representative (USTR) owes the public a detailed explanation about the steps the agencies are taking to ensure parents and their babies have access to infant formula.

According to reports, in 2021, the out of stock rates for infant formula were between 2 and 8 percent.<sup>3</sup> By the end of April 2022, an estimated 40 percent of U.S. baby formula supplies were out of stock.<sup>4</sup> The ongoing shortages are reportedly the result of supply chain and labor issues.<sup>5</sup>

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<sup>1</sup> Breck Dumas, *Baby formula shortage hits 'crisis' level, sparking panic in parents across US*, Fox Business (May 10, 2022), available at <https://www.foxbusiness.com/economy/baby-formula-shortage-sparking-panic-moms-parents-u-s>.

<sup>2</sup> Rob Wile, *Over 40 percent of America's baby formula supplies are out of stock*, NBC News (May 9, 2022), available at <https://www.nbcnews.com/business/consumer/baby-formula-shortage-recall-low-inventory-rcna27937>.

<sup>3</sup> Parija Kavilanz and Ramishah Maruf, *Baby formula shortage hitting US is getting worse following recall on numerous brands*, ABC (May 7, 2022), available at <https://abc7chicago.com/baby-formula-shortage-infant-similac-recall/11831056/>.

<sup>4</sup> *Supra* note 2.

<sup>5</sup> Jennifer Maloney and Sharon Terlep, *Baby Formula Is Hard to Find. Brands and Stores Are Divided Over Why.*, The Wall Street Journal (Jan. 12, 2022), available at <https://www.wsj.com/articles/baby-formula-is-hard-to-find-brands-and-stores-are-divided-over-why-11641983401>.

The February 2022 shutdown of a major formula plant in Sturgis, Michigan, is also contributing to the shortages.<sup>6</sup> FDA investigated the Sturgis plant in mid-February 2022 in response to complaints of a rare bacterial infection in four babies.<sup>7</sup> The FDA reportedly found safety violations and five strains of bacteria at the plant, although the strains apparently do not match the bacteria of the illnesses.<sup>8</sup>

Recently, the White House press secretary Jen Psaki stated the FDA is “working around the clock” to address the formula shortage.<sup>9</sup> On May 10, 2022, you stated that FDA is “doing everything in our power to ensure there is adequate product available where and when [consumers] need it.”<sup>10</sup> However, the Biden administration is not doing all it can to increase product availability. For instance, the federal government could eliminate tariffs of up to 17.5 percent and tariff rate quotas (TRQs) on imported infant formula.<sup>11</sup>

As hard-working American parents struggle to find infant formula, a recent news report indicated that illegal immigrants detained by Border Patrol may not be experiencing these difficulties.<sup>12</sup> A Member of Congress reportedly obtained photographs from a Border Patrol agent showing that shelves at a Customs and Border Protection (CBP) detention center in McAllen, Texas are stocked with “‘pallets’ of baby formula.”<sup>13</sup> The lawmaker claimed that “‘they’re receiving pallets and more pallets of baby formula at the border.”<sup>14 15</sup>

The assurances made by an untrustworthy administration and the lack of action do little to subdue the frustrations and anxieties of many parents that see a dwindling supply of infant formula for their babies. The American people and parents have a right to be angry. In order to better understand the steps the FDA is taking to alleviate supply chain constraints and barriers to production, please provide the following information:

1. What specific steps has FDA taken to address infant formula shortages?
2. When will parents be able to feel confident that infant formula is no longer in short supply?

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<sup>6</sup> Helen Bottemiller Evich, *‘I don’t know how my son will survive’: Inside the dangerous shortage of specialty formulas*, Politico (May 7, 2022), available at <https://www.politico.com/news/2022/05/07/i-dont-know-how-my-son-will-survive-inside-the-dangerous-shortage-of-specialty-formulas-00030787>.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> Allie Mallow, *FDA is ‘working around the clock’ to address baby formula shortage, Psaki says*, CNN (May 11, 2022), available at <https://www.cnn.com/2022/05/09/politics/fda-baby-formula-shortage/index.html>.

<sup>10</sup> Press Release, *FDA Takes Important Steps to Improve Supply of Infant and Specialty Formula Products*, Food and Drug Administration, May 10, 2022, <https://www.fda.gov/news-events/press-announcements/fda-takes-important-steps-improve-supply-infant-and-specialty-formula-products>.

<sup>11</sup> James Freeman, *The Cruellest Shortage*, The Wall Street Journal (May 10, 2022), available at <https://www.wsj.com/articles/the-cruellest-shortage-11652217835>.

<sup>12</sup> Paul Bedard, *Illegal migrants first to get ‘pallets’ of hard-to-find baby formula*, Wash. Examiner, May 12, 2022, <https://www.washingtonexaminer.com/news/washington-secrets/illegal-migrants-first-to-get-pallets-of-hard-to-find-baby-formula>.

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

3. The total amount of infant formula the federal government currently owns or is under contract to receive. The total amount of infant formula provided to illegal immigrants by CBP since August 1, 2021.
4. Has the Michigan plant restarted operations? If not, when does FDA expect this plant to be back online? Is Abbott Nutrition having issues with shipping products from its facility in Ireland?
5. Are there specific regulations that prevent additional domestic production of infant formula?
6. Has the FDA, DHS or USTR considered suspending regulations or tariffs, or providing flexibility to infant formula manufacturers to address the shortages? If not, why not?

Please provide this information as soon as possible but no later than May 27, 2022.  
Thank you for your attention to this important matter.

Sincerely,



Ron Johnson  
United States Senator