

United States Senate

February 21, 2023

VIA ELECTRONIC DELIVERY

The Honorable Joseph R. Biden, Jr.
President of the United States
The White House
1600 Pennsylvania Avenue, NW
Washington, D.C. 20500

Dear President Biden:

Thank you for your continued efforts to support American families and their babies during our Nation's infant formula shortage. I write to express my concerns regarding recent reports that families across the country continue to struggle to find the formula their child desperately needs, despite the progress our country has made to increase stock of infant formula products. In light of these troubling reports, I urge you to implement additional measures that will help ensure America's babies remain fed and will support our Nation's formula suppliers by temporarily suspending tariffs on select infant formula products approved for the U.S. market by the U.S. Food and Drug Administration (FDA), as authorized by Section 318(a) of the Tariff Act of 1930.

Last year, Congress passed and sent to your desk the Formula Act, which temporarily waived tariff duties on many infant formula products. In conjunction with these waived tariffs, the U.S. Food and Drug Administration (FDA) issued a guidance document to industry, announcing its decision to temporarily exercise enforcement discretion on foreign formula. This enforcement discretion allowed foreign manufacturers of infant formula products to apply for entry into the U.S. market on a case-by-case basis, upon the completion of a review of the formula product's safety information and nutritional adequacy. To ensure the safety of these products, FDA required manufacturers disclose information regarding a product's complete list of nutrients and ingredients, a copy of the product label and description of packaging, current or anticipated inventory of the formula, microbiological testing results and facility inspection history. Many foreign-made formula products successfully passed these requirements and entered the U.S. market, greatly easing the effects of the shortage heightened by the Abbott recall. Unfortunately, these temporary tariff exemptions provided by the Formula Act expired on December 31, 2022.

It is clear that actions taken by your administration were engineered to support a stable supply of infant formula products in the U.S. for years to come. In January, FDA announced its intention to increase the diversity and supply of infant formula in this country by providing a pathway for manufacturers who received a letter of enforcement discretion and distributed or imported approved infant formula products during its temporary discretion period, to continue marketing their products in the United States until 2025, while they work to meet FDA's requirements to permanently remain in the U.S. market. I can ascertain from these actions that FDA remains

confident in the quality of these products, recognizes the importance of diversifying our sourcing of these irreplaceable foods and understands the benefits these products provide to the U.S. market as American-made inventory continues to recover.

As you may know, while quantities of infant formula have increased since the height of the shortage, families continue to report low stock in certain parts of the country. Current levels of infant formula are also below levels of stock reported before the peak of the formula shortage in May and June of 2022. It is especially troubling that many families with infants with special medical needs report having a particularly hard time finding formula products that are made with their child's special medical needs in mind. Surveys conducted by the U.S. Census Bureau in early to mid-January confirm these findings, reporting that around 16 percent of parents surveyed mentioned they still had difficulty finding infant formula in the past seven days. Even Reckitt Benckiser, producers of the largest brand of infant formula on the American market, Enfamil, shared these sentiments, admitting the formula shortage will "continue to persist to some degree until the spring."

Despite clear indications that the supply of infant formula in the United States continues to be critically low, the reimposition of the tariffs on infant formula are guaranteed to increase the price of these products, which may prompt foreign manufacturers to import or produce fewer products for the U.S. market and unintentionally force the country back into a severe formula shortage. Some economists predict that the increased price of imported infant formula will prompt retailers to reconsider carrying foreign-made brands or limit their purchasing of these products. This will inadvertently increase demand for domestic product that, unfortunately, American manufacturers are currently unable to support. It is clear such actions will hamper recovery efforts to move past this shortage and will further inflict harm on families desperate to feed their children, especially for families with children that have special medical needs or dietary restrictions. The reimposition of tariffs on infant formula will also have a devastating effect on families struggling to make ends meet, particularly for families who are barely able to afford formula yet are unable to receive Federal assistance. The increased cost of these tariffed products is often passed down to the consumer, who must now pay more for this sole source of nutrition for their young child, especially as store shelves remain dangerously bare and parents are left without a choice.

Given how important this sole source of nutrition is for infants and the harm another shortage will bring to their health and welfare, I urge you to continue investing in additional mitigation efforts and contingency plans that will help ease the infant formula shortage the country is still experiencing a year after the Abbott plant in Sturgis, Michigan temporarily shut down. I recognize that America's manufacturers are working around the clock to produce more infant formula than ever before, and strongly believe a temporary suspension of infant formula tariffs will allow domestic manufacturers to increase supply, stockpile their products, expand manufacturing capabilities, strengthen supply chains and ultimately, prevent another infant formula shortage from ever occurring in the United States. I urge you to utilize your executive authority, provided by Section 318(a) of the Tariff Act of 1930, to temporarily restore tariff exemptions for infant formula products produced by foreign manufacturers who have notified the FDA of their intent to remain in the U.S. market through FDA's enforcement discretion, until at least early summer and to continue supporting American families and their young children.

Thank you for your continued efforts on this topic and I look forward to working with you to ensure our Nation's children remain healthy and fed.

Sincerely,



Tammy Duckworth
United States Senator