



Consumer Federation of America

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
The Capitol
Washington, DC 20515

The Honorable Charles Schumer
Majority Leader
U.S. Senate
The Capitol
Washington, DC 20510

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
The Capitol
Washington, DC 20515

The Honorable Mitch McConnell
Minority Leader
U.S. Senate
The Capitol
Washington, DC 20510

June 29, 2022

Re: Support for Measures to Ensure Infant Formula Safety

Dear Speaker Pelosi, Majority Leader Schumer, Minority Leader McCarthy and Minority Leader McConnell:

Consumer Federation of America writes to urge the United States Congress to pass critical legislation that will help to protect the nation's most vulnerable consumers from contaminated infant formula. Over four months since the February shutdown of Abbott Laboratories' infant formula manufacturing plant in Sturgis, Michigan, families continue to struggle to find infant formula, with 27% of powder formulas reportedly out of stock at retailers across the nation during the week ending June 19. These shortages are particularly acute for specialty formulas that many premature and other vulnerable infants depend upon. Congress must act boldly to prevent these problems from arising again, with the understanding that food safety lapses, and deficiencies in the food safety regulatory system, are the root cause of the shortages.

The Food and Drug Administration Safety and Landmark Advancements Act of 2022 ("FDASLA Act") (S.4348) will help to avoid another infant formula crisis. This bill will ensure that FDA inspectors visit every single registered infant formula manufacturing facility at least once a year, and that inspectors reinspect facilities "in a timely manner" where doing so may be necessary "to ensure that such manufacturer completed any remediation actions or addressed any deficiencies." This mandate will help to ensure that FDA prioritizes inspection of infant formula plants, particularly those where compliance issues are found. Notably, FDA inspectors found a litany of sanitation violations at the Sturgis plant in September of 2019, and even collected environmental samples that tested positive for *Cronobacter sakazakii*, the pathogen that killed at least two infants that consumed formula from the plant. Nevertheless, inspectors did not visit the plant again until two years later. The FDASLA Act's inspection mandate will prohibit such delays. The FDASLA Act will also help to ensure that FDA makes other necessary changes to prevent future shortages of infant formula, by setting up an Office of Critical Foods within FDA's Center for Food Safety and Applied Nutrition and commissioning a report from

the National Academies of Sciences, Engineering, and Medicine that should direct more comprehensive reform.

Implementing these initiatives, and protecting America's most vulnerable consumers from deadly foodborne pathogens in general, will require a significant increase in resources for FDA. We urge you to support at least the roughly 9.7% increase to the Center for Food Safety and Applied Nutrition's budget that was approved by the House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies earlier this month. As the report for that bill notes, it was "developed during the infant formula shortage in the spring of 2022. That crisis revealed the FDA had only nine people in the office that regulates infant formula. This raises a concern about how many other key offices at the agency are also severely understaffed." Congress should not wait until the next food safety related crisis for these staffing problems to be resolved.

Thank you for your consideration.

Sincerely,

Thomas Gremillion
Director of Food Policy
Consumer Federation of America