United States Senate
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
WASHINGTON, DC 20510–6300

October 5, 2022

Delivered via Email

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

Dear Commissioner Califf:

On September 20, 2022, the Food and Drug Administration (FDA) published an internal review of the agency's actions related to the recent infant formula supply shortage. I am disappointed that the results of the agency's after-action review falls woefully short of the substantive analysis and accountability needed to serve and protect American families. The infant formula crisis impacted families across this nation, with nationwide out-of-stock rates of formula reaching greater than 40 percent, while statewide out-of-stock rates soared to as high as 89 percent. FDA is responsible for regulating infant formula, yet when the public depended on its expertise, the FDA failed.

FDA's report – titled as an "evaluation" of the infant formula response – neglects its most basic task to assess the internal problems that created a nationwide shortage of infant formula and provide recommendations to prevent such problems in the future. After nearly four months of work that included interviews of over 60 FDA employees, FDA identified 15 findings, categorized into five "major areas of need." However, these findings fail to identify with any helpful level of specificity the problems with FDA's response to the crisis or concrete steps that FDA can take to improve its response to future crises. For example, 12 of the 15 recommendations contained in the report recommend that FDA either "review," "evaluate," or "update" existing policies or procedures, and the other three recommendations advise that FDA request more money. In short, this document offers little more than a vague plan to make a plan, someday.

The report provides no accountability for FDA's failures. There is no explanation for the months-long delays between FDA becoming aware of problems related to infant formula production or supply and taking action to help address such problems. There is no mention of FDA's inspections of infant formula facilities and the results from those inspections, or analysis of its decisions to restrict supply by shutting down one of those facilities. There is also no mention of FDA's irresponsible decision to stop food safety inspections during the COVID-19 pandemic. There is no review of the steps FDA took to try to expand formula supply, or an evaluation of which steps worked well, which did not, and which should have happened earlier. There is no plan for how FDA will help alleviate the supply limitations that continue to plague parents across the country. There is no reference to the need for improved collaboration between FDA and industry to reduce the risk of another disruption in the domestic supply of infant formula, or the need to incentivize additional competition and supply.

Instead of accounting for what went wrong, and taking ownership of serious shortfalls in judgement and action, FDA used this report as yet another opportunity to ask for more money and more authority. Multiple times, FDA noted the lack of resources and authorities, concluding that "if FDA is expected to do more, it needs more." This shows an appalling lack of awareness of FDA's existing budget and priorities. In 1994, FDA received approximately $800 million in appropriations from Congress – today, the agency receives more than $3 billion in annual appropriations. FDA spends more than $1.1 billion per year on its food activities, coupled with extensive and flexible regulatory authorities. Yet while FDA presided over and exacerbated this crisis, you instead focused on what we can call "French dressing," what ingredients can be in yogurt, how best to color salmon, and helped people be happy about their grated cheese.

Before FDA can get one more dollar, it needs to show more responsibility and accountability—namely, that the agency can be responsible stewards of the expansive authorities and significant funding Congress has already provided and that it will hold itself accountable for its own mistakes. The report concluded that there was no single action to explain the crisis, but rather a "confluence of systemic vulnerabilities" within the agency and the industry that need to be addressed. Complexity is no excuse for a lack of accountability. Decrying "systemic vulnerabilities," without identifying specific, concrete problems and solutions, is a recipe for FDA to repeat its failed playbook in the future.

I cannot support rewarding FDA with additional resources after a failure of this magnitude, especially when this report demonstrates that the agency does not take accountability seriously. Parents across the country should never again face the fear and panic of another formula shortage. For these reasons, I respectfully request that FDA provide written responses to the below questions by October 21, 2022:

1) Over the past two years, there have been a number of events that led to an acute infant formula shortage and continued supply difficulties. These include multiple inspections, infant deaths, whistleblower complaints, recalls, and shutdowns of infant formula plants. Please provide a detailed timeline and analysis of FDA's actions during the last 3 years, including an assessment of both the substance and timing of those actions.

2) The report contains 15 recommendations for FDA action, almost all of which involve the need to "evaluate" or "review" existing policies and procedures.

    a. Please provide a comprehensive timeline and work plan for FDA to conduct the activities contained in the report's recommendations, or an explanation for why FDA will not be conducting the recommended activities. Please include deadlines, if any, for completing such work.
    b. Please provide the number of full time equivalents (FTEs) assigned to each task.

3) In conducting the review that led to this report, did the evaluation team speak to individuals who are not FDA employees, such as individuals from FDA-regulated entities who interacted with FDA during this crisis? If so, please provide a list of any such individuals or entities and when these interactions occurred. If not, why not?

4) One of the main five findings of the internal review was that there was a need to update emergency response systems to handle multiple public health emergencies at once.

    a. Please provide the number of FTEs within the Center for Food Safety and Nutrition (CFSAN) that are working on the COVID-19 response, the total number of FTEs within

CFSAN that are working on the infant formula supply shortage response, and the total number of FTEs that are overlapping on both projects.

b. Please provide documentation of when the emergency response systems were last updated, and what the FDA's schedule is for regularly evaluating such systems and updating as necessary

5) The report found that investigators of infant formula manufacturing facilities "receive limited infant formula-specific training."
   a. What does the current training for infant formula facility inspectors consist of today? Please provide copies of the training manuals, checklists, and other training materials.
   b. Why does FDA not have adequate training for infant formula facility inspectors?
   c. What processes does FDA have in place to review and update the adequacy and quality of investigator training?

6) During the peak of the shortage, many consumers switched to formula products manufactured abroad. Domestic supply has still not returned to standard levels. What actions is the agency taking to increase domestic formula supply through increased manufacturing capacity and facilitating new entrants into this market? How many new entrants into the infant formula market has FDA authorized in the last 3, 5, and 10 years?

7) In FY 2021, FDA received 42 submissions for new infant formulas. FDA was only able to review 15 – one-third of those submitted—within the 90-day statutory timeline. Why was FDA only able to review one-third of the submissions within the 90-day deadline? What steps is FDA taking to speed up its review of infant formula submissions?

8) In the FY 2023 budget request, FDA has requested an increase of $181.3 million on top of its existing budget to total $1.6 billion for food safety. Please provide the amount of funding that will be directed to the infant formula program and related activities, including a breakdown of activities within such program.

Thank you for your attention to this matter. I look forward to receiving a prompt reply.

Sincerely,

Richard Burr