# SAFE FOOD COALITION

The Honorable Kevin McCarthy
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 Hakeem Jeffries
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

April 12, 2023

**Re: Gaps in U.S. Food and Drug Administration Food Safety Authority**

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

The undersigned members of the Safe Food Coalition write in support of recent legislative proposals from the U.S. Food and Drug Administration (FDA) for FY 2024 that are necessary to ensure the safety of the food supply for U.S. consumers. Specifically, we urge you to act without delay to give FDA the authority to conduct remote inspections, to require infant formula and baby food manufacturers to test for toxic contaminants and report positive test results to FDA, and to enable FDA to share critical inspection and enforcement information with state regulatory partners.

As detailed by the agency in its recent Summary of FY 2024 Legislative Proposals, these reforms address critical deficiencies in FDA's capacity to keep the food supply safe. The COVID-19 pandemic exacerbated the impracticalities associated with relying exclusively on in-person inspection, culminating in the closure of the Abbott Laboratories' Sturgis, Michigan facility and the ensuing infant formula crisis. FDA has found that the inability to remotely request records delayed FDA's response to complaints about adulterated products from Abbott Laboratories. Empowering FDA to conduct remote regulatory assessments will help to avoid similar crises and to better determine how the agency can deploy inspectors on the ground.

By the same token, requiring infant formula and other baby food manufacturers to proactively report positive test results for pathogens like *Cronobacter sakazakii* and *Salmonella*, and for toxic elements, such as arsenic, cadmium, lead and mercury, will help to protect public health. Current rules require infant

formula manufacturers to test each product lot for pathogens, but FDA can remain oblivious to positive test results so long as its inspectors do not physically visit the production facility. In part due to pandemic pressures, two years passed between inspections of the Abbott Laboratories' Sturgis facility in the period leading up to the infant formula recall. Had product testing results been shared with the agency, inspectors likely would have visited much earlier, and discovered the insanitary conditions that prompted the recall. Similarly, two 2021 Congressional reports found that baby food manufacturers knowingly marketed products containing high levels of toxic heavy metals. Giving FDA authority to require environmental testing and toxic element testing for these products, and to require notification of anticipated significant interruptions in the supply of these products, will provide further assurance that the highly consolidated infant formula manufacturing sector reliably produces safe product for U.S. consumers.

Finally, FDA needs new authorities to share information with its regulatory partners. As consumer groups, we typically advocate for laws requiring more transparency. Under the current law, however, FDA cannot share critical inspection and enforcement information with state regulatory partners out of concern that doing so will compromise confidentiality protections under federal law because the states may subsequently make the shared data public under state sunshine laws. This has led to absurd results. Following FDA inspections, state regulators have reportedly received requests from the agency for assistance with enforcement actions against an out-of-compliance facility, only to find that the FDA inspection data accompanying the request is so heavily redacted that they cannot determine the basis for an enforcement action, and so must duplicate work already undertaken by FDA. To overcome this information sharing barrier, limited preemption of state and local "sunshine" laws, sufficient to prevent the disclosure of confidential federal documents, is appropriate.

In conclusion, we support FDA's request for additional legislative authorities as described under the headings Expanding Information Disclosure Authorities with States, Expansion of FDA Tools to Provide Oversight of FDA-Regulated Products, and Product Testing Requirements for Foods Marketed for Consumption by Infants and Young Children in the agency's Summary of FY 2024 Legislative Proposals.

We would be happy to discuss this request with your staff. If you have questions, please contact Thomas Gremillion at the number above or by email: tgremillion@consumerfed.org.

Thank you for your consideration of this request.

Sincerely,

Center for Food Safety
Center for Science in the Public Interest
Consumer Federation of America
Consumer Reports
Stop Foodborne Illness