Congress of the United States
Washington, DC 20515

June 24, 2022

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Califf:

After the tragic deaths of two infants and the ensuing baby formula shortage—caused by the contamination of baby formula at the Abbott plant in Sturgis, Michigan—it is clear that we need better industry oversight and regulation for all categories of baby and toddler foods. We are especially concerned about the continued presence of toxic heavy metals in these foods, and the threat this poses to both public health and food supply in the U.S. We therefore respectfully request information on the Food and Drug Administration's (FDA) timeline for issuing draft action levels for lead; the likelihood of broader delays in the timeline for setting action levels on arsenic, cadmium, and mercury; and the potential impact of Congressional support for FDA's FY23 legislative proposals to accelerate the *Closer to Zero* timeline.

An investigation by the House Oversight Subcommittee on Economic and Consumer Policy revealed over one year ago that many popular baby foods contain dangerously high levels of lead, arsenic, cadmium, and mercury.[1] Consumption of these toxic heavy metals, even in extremely small quantities, can have detrimental impacts on a child's neurological development, such as permanently decreased IQ, behavioral disorders, and lower academic achievement.[2] Recent investigative reporting reveals that FDA knew about toxic heavy metals in baby and toddler food since as early as 2017, and yet, even after four years of formally working on the issue, the agency had not even formulated a concrete action plan until the congressional investigation by the Economic and Consumer Policy Subcommittee.[3] Only after this groundbreaking investigation and the accompanying public outrage did FDA announce the *Closer to Zero* plan, which lays out a timeline for reducing exposure to toxic elements from foods eaten by babies and young children.[4]

Now, FDA has missed the first deadline in the *Closer to Zero* plan. Phase 1 called for FDA to issue draft action levels for lead in categories of foods consumed by babies and young children by April 2022.[5] We understand that FDA submitted draft action levels for lead to the Office of Management and Budget (OMB) for review on April 14, 2022, but industry and the American people are still awaiting this guidance. Submitting draft action levels to OMB for review is not

[1] U.S. House Oversight Subcommittee on Economic and Consumer Policy, "Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury," 2/21
[2] U.S. House Oversight Subcommittee on Economic and Consumer Policy, "Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury," 2/21
[3] *POLITICO*, "The FDA's Food Failure," 4/22
[4] Food and Drug Administration, "Closer to Zero: Action Plan for Baby Foods," 4/21
[5] Food and Drug Administration, "Closer to Zero: Action Plan for Baby Foods," 4/21

tantamount to FDA issuing draft action levels. This does not meet the timeline laid out in the *Closer to Zero* action plan, and we are concerned that FDA's failure to meet the Phase 1 deadline for lead may indicate future delays in the *Closer to Zero* timeline for issuing drafting action levels for arsenic, cadmium, and mercury.

We are encouraged, however, to see FDA's FY23 Legislative Proposals call for new industry testing and reporting requirements—specifically requiring companies to test final products meant for consumption by infants and young children, to maintain those records, and to provide FDA remote access whenever necessary.[6] It is clear from the contamination of baby formula at the Abbott plant in Sturgis, Michigan that testing and reporting requirements are necessary for FDA to properly regulate infant and toddler foods, and we are interested to hear how these requirements would impact FDA's *Closer to Zero* action plan.

We therefore respectfully request answers to the following questions by July 8, 2022:

- When will FDA issue proposed action levels for lead in all categories of foods consumed by babies and young children?
- Is FDA on track to meet the timeline for Phases 2 and 3 of the *Closer to Zero* action plan? What are the FDA's target dates for issuing proposed action levels for arsenic, cadmium, and mercury?
- While we are encouraged to see FDA call for greater authority to enforce testing and reporting requirements in its FY 2023 Legislative Proposals,[7] can you provide more detailed information on how testing and reporting requirements will impact FDA's implementation of the *Closer to Zero* plan?

We appreciate FDA's swift action in addressing the current baby formula shortage, and we urge you to take equally substantive and rapid action to mitigate children's dietary exposure to toxic heavy metals.

Sincerely,

Raja Krishnamoorthi
Member of Congress

Tammy Duckworth
United States Senator

Tony Cárdenas
Member of Congress

[6] Food and Drug Administration, "Executive Summary of FY 2023 Legislative Proposals," 3/22
[7] Food and Drug Administration, "Executive Summary of FY 2023 Legislative Proposals," 3/22

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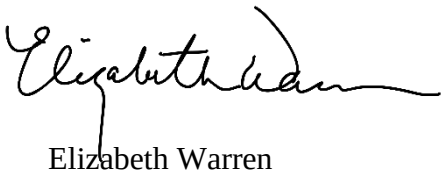

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