

Congress of the United States

Washington, DC 20515

November 30, 2023

Dr. Robert Califf
Commissioner
U.S. Food and Drug Administration
c/o Dockets Management Staff (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Public Docket No. FDA-2022-D-0278: Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry

Dear Commissioner Califf:

In light of alarming recent reports of elevated levels of lead detected in certain food targeted at toddlers and young children, we write to urge the Food and Drug Administration (FDA) to swiftly finalize its *Closer to Zero* guidance for industry, Action Levels for Lead in Food Intended for Babies and Young Children. We also request FDA include the potential source of these recent cases of reported lead poisoning in young children, food puree pouches, in the finalized *Closer to Zero* guidance for industry. Last year, we [wrote](#) to you, requesting an update on when FDA would finalize action levels for lead in juices and processed baby foods, as well as on FDA's timeframe for its other *Closer to Zero* objectives. In light of recent harm caused by certain cinnamon applesauce and fruit puree products, it is clear that the agency must prioritize the work on heavy metal action levels.

Lead is toxic to people of all ages, but can be especially harmful to infants and young children. Lead exposure in children can potentially cause significant and irreversible damage to the brain and nervous system and slow a child's growth and development.

All food manufacturers have a responsibility by law to meaningfully minimize or prevent chemical hazards, including through preventive controls to reduce or eliminate the presence of lead in their products. However, as a 2021 investigation by the House Oversight Subcommittee on Economic and Consumer Policy revealed, foods commonly eaten by babies and young children must be subject to higher standards of reduced heavy metals because these consumers are more vulnerable to the harmful effects of contaminants.

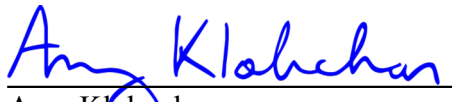
That is why it is particularly distressing to learn that elevated levels of lead recently have been detected in food puree pouches, which are intended for toddlers and young children. Specifically, 52 cases of elevated blood lead levels in children have been potentially linked to Apple Cinnamon Fruit Puree pouches sold under WanaBana, Weis, and Schnucks brands. In fact, a finished product sample of WanaBana Apple Cinnamon Puree detected a lead level of 2.18 parts per million, which is 200 times greater than the action level the FDA has proposed in draft guidance for food products marketed and intended for babies and young children.


While we are pleased that the FDA has taken initial steps to address elevated lead levels in food, including launching a reorganization of the newly-unified Human Foods Program this year and appointing its first Deputy Commissioner for Human Foods in September, these recent cases of child lead poisoning make clear that more


must be done. The *Closer to Zero* initiative is critical to provide information to industry on actions needed to reduce lead levels in food, yet progress made under the *Closer to Zero* action plan remains slow. We remain committed to working with our colleagues to secure funding for this important program.


We urge the Human Foods Program to use its new decision-making authority to swiftly finalize this guidance for industry regarding action levels for lead and other heavy metals in foods intended for babies and young children. Further, we request that food puree pouches similar to those recently recalled be included in the finalized guidance. Products such as these, which are heavily marketed to toddlers and children, must receive sufficient monitoring and testing for lead and other heavy metals. We stand ready to work with the FDA on achieving the *Closer to Zero* objectives and look forward to the finalized guidance.

Sincerely,

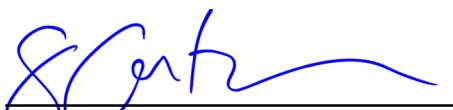

Amy Klobuchar
United States Senator


Raja Krishnamoorthi
Member of Congress


Tammy Duckworth
United States Senator


Tony Cardenas
Member of Congress


Katie Porter
Member of Congress


Sean Casten
Member of Congress


Jared Moskowitz
Member of Congress

A handwritten signature in black ink, reading "Rosa L. DeLauro". The signature is written in a cursive style with a large, stylized "R" and "D".

Rosa L. DeLauro
Member of Congress