Congress of the United States

Washington, DC 20515

December 18, 2023

Robert Califf, MD Commissioner U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Mandy Cohen, MD, MPH Director Centers for Disease Control and Prevention 395 E Street, SW Washington, DC 20024

Dear Commissioner Califf and Director Cohen,

We write with serious concerns following a growing number of reports from across the country that children have been poisoned by lead-tainted applesauce.

On November 13, 2023, the Centers for Disease Control and Prevention (CDC) issued an alert advising parents and caregivers of children who may have consumed affected products to have the children tested for lead. This was prompted by reports from multiple states of high blood lead levels in children who had consumed applesauce products containing contaminated cinnamon.¹ As of December 11, 2023, the U.S. Food and Drug Administration (FDA) has received 65 reports of illness in 27 states potentially linked to these now-recalled products.² An investigation by The Washington Post, published on December 9, 2023, identified at least 118 suspected or confirmed cases in 31 states believed to be connected to cinnamon in applesauce.³

Alarmingly, some of the applesauce pouches tested were found to contain over 500 times the acceptable amount of lead for young children, and some children had been consuming multiple pouches a day.³ According to the Agency for Toxic Substances and Disease Registry, children absorb significantly more ingested lead than adults —about 50 percent of ingested lead after a meal and up to 100 percent on an empty stomach.⁴ As there is no safe level of lead in blood, we are gravely concerned about the short- and long-term health risks to these children.⁵ Potential consequences of lead poisoning include vomiting, weight loss, fatigue, seizures, hearing loss, learning difficulties, and developmental delays.⁶

Families and other consumers trust regulators to ensure that food products meet minimum safety standards. These reports are extremely troubling on their own—especially given the emerging possibility that the cinnamon may have been intentionally contaminated with lead. However, they also shed light on larger issues around the lack of federal standards for lead in most foods, including those consumed by babies and young children, and that product testing is generally not required.

¹ https://emergency.cdc.gov/han/2023/han00500.asp

² https://www.fda.gov/food/outbreaks-foodborne-illness/investigation-elevated-lead-levels-cinnamon-applesauce-pouches-november-2023

³ https://www.washingtonpost.com/wellness/2023/12/09/applesauce-recall-lead-poisoning-cinnamon

⁴ https://www.atsdr.cdc.gov/csem/leadtoxicity/biologic_fate.html

⁵ https://www.who.int/news-room/fact-sheets/detail/lead-poisoning-and-health

⁶ https://www.mayoclinic.org/diseases-conditions/lead-poisoning/symptoms-causes/syc-20354717

⁷ https://www.politico.com/news/2023/12/14/applesauce-pouches-may-have-been-contaminated-on-purpose-fda-foods-chief-says-00131797

In February 2021, a congressional report revealed that baby foods sold in the U.S. can contain dangerously high levels of toxic elements such as lead.⁸ Subsequently, FDA launched the Closer to Zero action plan, aiming to reduce lead, arsenic, cadmium, and mercury in foods consumed by babies and young children.^{9,10} More than two years later, FDA has issued two draft guidance documents proposing limits on lead in juices and baby foods but has not finalized standards.¹⁰

In light of these recent events, we call on FDA to expedite efforts on the Closer to Zero plan and to maximize public health protection when setting action levels for foods. We also urge FDA to expand its current draft guidance on foods intended for babies and young children to ensure that the applesauce pouches implicated in this situation and other foods commonly consumed by young children are covered. Finally, we ask FDA to release any testing results it has received for products implicated in the current applesauce recall.

Over the past several weeks, we have appreciated the efforts of public health workers across the country to trace lead exposures from these applesauce pouches and provide guidance to families. As more cases are being identified, we want to particularly uplift disadvantaged and vulnerable communities where children may be disproportionately affected. This may be the case as children suffer the cumulative effects of lead exposure from multiple sources such as housing and drinking water in addition to contaminated food products. We urge FDA and CDC to take all steps possible to broadly disseminate information on this issue and ensure that all families worried about potential lead exposures are able to access appropriate testing and treatment for their children.

Thank you for your dedication to safeguarding public health. We look forward to working together to protect children across the country from the harmful effects of lead and other food contaminants.

Sincerely,

Jennifer L. McClellan Member of Congress

 $^{^{8}\ \}underline{\text{https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04\%20ECP\%20Baby\%20Food\%20Staff\%20Report.pdf}$

 $^{^{9}\ \}underline{\text{https://www.fda.gov/news-events/press-announcements/fda-releases-action-plan-reducing-exposure-toxic-elements-foods-babies-young-children}$

 $^{^{10} \ \}underline{\text{https://www.fda.gov/food/environmental-contaminants-food/closer-zero-reducing-childhood-exposure-contaminants-foods}$

Member of Congress

Manette Diaz Barragán

Nanette Diaz Barragán Member of Congress

Kathy Castor Member of Congress

Donald G. Davis Member of Congress

Chris Pappas

Member of Congress

Katie Porter

Member of Congress

Shri Thanedar

Member of Congress

David J. Trone

Member of Congress

Jennifer Wexton

Member of Congress