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ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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January 19, 2024

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

Dear Commissioner Califf:

The Committee writes to express our concerns and request an immediate briefing on the reported lead and chromium contamination of applesauce pouches sold in the United States. On November 9, 2023, the Food and Drug Administration (FDA) recalled three applesauce brands—Weis, WanaBana, and Schnucks—“due to reports of elevated levels of lead.”¹ In a statement, the FDA’s Deputy Commissioner for Human Foods, Jim Jones, indicated that recent lead contamination in applesauce pouches may have been an intentional, economically motivated act by a foreign supplier of cinnamon for the recalled products.² As of January 8, 2024, the FDA has received 87 confirmed complaints/adverse event reports linked to the recalled product.³ The Centers for Disease Control and Prevention (CDC) reports a total of 321 cases from 38 different states.⁴ Reports suggest more than 60 children under the age of six in the United States have tested positive for lead poisoning.⁵ Children in this age range are more susceptible to lead poisoning,

¹ Press Release, FDA, WanaBana Recalls WanaBana, Weis, and Schnucks Apple Cinnamon Fruit Puree Pouches & Cinnamon Apple Sauce Due to Elevated Lead Levels (Nov. 9, 2023), <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/wanabana-recalls-wanabana-weis-and-schnucks-apple-cinnamon-fruit-puree-pouches-cinnamon-apple-sauce>.

² Marcia Brown & Meredith Lee Hill, *Applesauce Pouches May Have Been Contaminated on Purpose, FDA Foods Chief Says*, Politico (Dec. 14, 2023), <https://www.politico.com/news/2023/12/14/applesauce-pouches-may-have-been-contaminated-on-purpose-fda-foods-chief-says-00131797>.

³ FDA, Investigation of Elevated Lead & Chromium Levels: Cinnamon Applesauce Pouches (November 2023), <https://www.fda.gov/food/outbreaks-foodborne-illness/investigation-elevated-lead-chromium-levels-cinnamon-applesauce-pouches-november-2023>.

⁴ *Id.*

⁵ Amanda Morris et al., *Applesauce Lead Cases in Kids Surge Amid Questions on FDA Oversight*, Washington Post (December 9, 2023), <https://www.washingtonpost.com/wellness/2023/12/09/applesauce-recall-lead-poisoning-cinnamon/>.

which makes our concerns about FDA's ability to address intentional product adulteration along the global supply chain particularly urgent.⁶

Though the FDA has in the past elevated concerns about unacceptably high levels of lead in some baby food, recent events raise whether more can be done to prevent and detect illicit food contamination.⁷ Therefore, the Committee urgently requests a detailed briefing on the FDA's suspicion of intentional lead contamination in applesauce pouches, particularly the steps undertaken for its investigation and measures for future prevention. It is crucial to understand the FDA's strategies for detecting and addressing intentional contamination in the food supply chain given the limited authority your agency has over contaminated cinnamon from abroad, which was identified as the potential source of this issue.⁸

We request a briefing as soon as possible, but no later than February 2, 2024. In preparation for the briefing, please be prepared to address the following matters, including but not limited to:

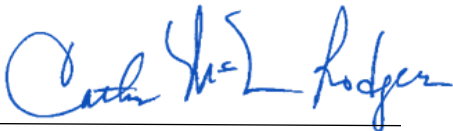
1. A timeline of events leading to the discovery of lead contamination in the three applesauce brands listed above.
2. How did the FDA determine that the adulteration of raw cinnamon may have been intentional?
3. How is the FDA collaborating with international partners, particularly Ecuadorian authorities, to investigate this issue thoroughly?
4. How is the FDA collaborating with domestic partners, including state departments of health, to investigate this issue thoroughly?
5. What steps have been taken to determine if other foods have been contaminated as a result of this supply chain vulnerability?
6. How, if at all, does the FDA's process for detecting lead contamination in food products differ for foods produced domestically from food produced abroad?
7. Since 2020, what has the FDA done to identify lead-contaminated foods and prevent them from reaching shelves?
8. Since 2020, how many recalls has the FDA issued related to lead contaminated foods? Of those, please specify how many were related to contamination products manufactured in America and how many were related to contamination abroad.

⁶ Know the Facts, Protect Your Child from Lead Exposure, Ctr. for Disease Control and Prevention (last visited Dec. 15, 2023) <https://www.cdc.gov/nceh/lead/docs/know-the-facts.html>.

⁷ See Sandee LaMotte, *FDA Proposes New Levels for Lead in Baby Food, But Critics Say More Action is Needed*, CNN (Jan. 30, 2023), <https://www.cnn.com/2023/01/24/health/baby-food-lead-levels-fda-wellness/index.html>; Press Release, Food and Drug Administration, *FDA Announces Action Levels for Lead in Categories of Processed Baby Foods* (Jan. 24, 2023), <https://www.fda.gov/news-events/press-announcements/fda-announces-action-levels-lead-categories-processed-baby-foods>.

9. What are the FDA's capabilities within its existing authorities to enhance monitoring and inspection processes to better detect and prevent intentional acts of lead contamination along the supply chain, including internationally, and what plans does the FDA have to use those authorities?
10. What additional resources or authorities are needed to better detect and prevent intentional acts of lead contamination along the supply chain, including along international supply chains?
11. Will the FDA commit to providing the Committee with rolling updates on the status of the investigation, including findings related to the suspected international contamination?

Sincerely,



Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce



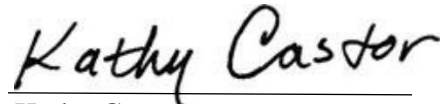
H. Morgan Griffith
Chair
Subcommittee on Oversight
and Investigations



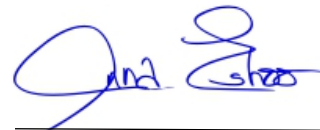
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