

United States Senate

December 14, 2023

The Honorable Robert M. Califf, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20993

Dear Commissioner Califf:

The Food and Drug Administration (FDA) plays an important role in safeguarding our nation's food and drug supply chain. Recently, we have seen troubling reports regarding recalls of certain products using cinnamon with high levels of heavy metals in them and the potential risks associated with sourcing our food products from untrustworthy countries like Communist China.

On October 28, 2023, the FDA issued a safety alert along with state agencies in North Carolina as it investigated reports of four children with elevated blood lead levels.¹ Initial reports show that the high lead levels were traced to cinnamon applesauce pouches. By October 31, the manufacturer initiated a voluntary recall of its apple cinnamon fruit puree pouches. As of November 17, there were 34 reports of illness across 20 states that are potentially linked to this recall.² The FDA reports that the detected lead levels are 200 times greater than the action level for lead levels the FDA has proposed in draft guidance for babies and young children.³

It appears that the high lead levels were associated with the cinnamon in this product, and not the applesauce. It also appears that the company that was selling these fruit pouches was sourcing cinnamon from an Ecuadorian supplier that may have been purchasing cinnamon from Asian countries, such as Communist China. High lead or heavy metal levels in spices, such as cinnamon, typically come from three potential sources: either high levels in the soil the product was grown in, potential contamination in the supply chain during processing, or economically motivated adulteration such as adding lead chromate to increase the product's weight.

¹ <https://www.fda.gov/food/outbreaks-foodborne-illness/investigation-elevated-lead-levels-cinnamon-applesauce-pouches-november-2023>

² <https://time.com/6336969/fda-applesauce-recall-wanabana-lead-cinnamon/>

³ <https://www.fda.gov/food/outbreaks-foodborne-illness/investigation-elevated-lead-levels-cinnamon-applesauce-pouches-november-2023>

A recent news article has the FDA investigating this incident as a case of potential economic adulteration.⁴ This is a serious issue because it demonstrates the vulnerability of the U.S. supply chain. Additionally, Communist China has been known to engage in economically motivated adulteration such as adding melamine (a chemical used in plastics) to infant formula which led to kidney failure in babies and at least six deaths.⁵ In 2008, companies based in Communist China used counterfeit precursor chemicals in the manufacturing of heparin, an anticoagulant, in a non-sterile environment. This led to the death of 81 people in the US and more incidents across 11 countries.⁶

This is not the first time that there have been warnings of the danger of heavy metals in herbs and spices, such as cinnamon. In 2021, Consumer Reports (CR) wrote of their testing and found, “Roughly one-third of the tested products, 40 in total, had high enough levels of arsenic, lead, and cadmium combined, on average, to pose a health concern for children when regularly consumed in typical serving sizes. Most raised concern for adults, too.”⁷ CR noted that the FDA can test herbs and spices shipped to the U.S. and block products from entry. This is important because “...most spices sold in the U.S. are grown abroad – in countries such as China, India, and Vietnam – and some research suggests that oversight of food production there is sometimes less rigorous.”

There are 22 million Floridians and more than 300 million Americans in this country that could be exposed to heavy metal in herbs and spices used in common food products. Given the importance of our food supply to protect our children and families, and the need for the FDA to act quickly to ensure families have the food they need to feed their children, please answer the following questions:

- What policies, if any, has the FDA instituted to help ensure that heavy metals are not in common herbs and spices for sale to American consumers, such as in the grocery store or found in prepared food?
- What is considered a safe level of lead in our food supply?
- Is the FDA investigating the sourcing of the cinnamon from this recall product?
- Are the relevant Ecuadorian authorities cooperating with the FDA, so that the origin of the tainted cinnamon will be discovered?
- Does the FDA know where and how the cinnamon was contaminated in the supply chain?

⁴ <https://www.politico.com/news/2023/12/14/applesauce-pouches-may-have-been-contaminated-on-purpose-fda-foods-chief-says-00131797>

⁵ <https://www.fda.gov/food/compliance-enforcement-food/economically-motivated-adulteration-food-fraud>

⁶ <https://www.nytimes.com/2008/04/22/health/policy/22fda.html>

⁷ <https://www.consumerreports.org/health/food-safety/your-herbs-and-spices-might-contain-arsenic-cadmium-and-lead-a6246621494/>

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- Is the FDA concerned that one of the largest producers of cinnamon is Communist China which has a history of deception and failing to take responsibility for their economically adulterated products?
- The supply chain has changed after COVID-19 and is more global than it has ever been. How has the FDA adapted to meet this new challenge?

I look forward to your prompt response so that the youngest and most vulnerable among us have access to the nutrition that they need. I urge the FDA to take swift and decisive actions to solve this important issue.

Sincerely,

A handwritten signature in blue ink, appearing to read "Rick Scott". The signature is stylized and cursive.

Rick Scott
United States Senator