Investigation of Elevated Lead Levels: Cinnamon Applesauce Pouches (November 2023)

Do not eat, sell, or serve multiple brands of recalled apple cinnamon fruit pouches. FDA's investigation is ongoing.

Product

Recalled cinnamon apple puree and applesauce products. Information on lot codes and UPCs can be found in the firm's recall announcement.

- Recalled WanaBana apple cinnamon fruit puree pouches
- Recalled Schnucks-brand cinnamon-flavored applesauce pouches and variety pack
- Recalled Weis-brand cinnamon applesauce pouches

Symptoms of Lead Toxicity

Lead is toxic to humans and can affect people of any age or health status. Protecting children from exposure to lead is particularly important because they are more susceptible to lead toxicity. Most children have no obvious immediate symptoms. Parents and caretakers should consult a healthcare provider if you suspect a child may have been exposed to lead. Short term exposure to lead could result in the following symptoms: headache; abdominal pain/colic; vomiting; anemia. Longer term exposure could result in the following additional symptoms: irritability; lethargy; fatigue; muscle aches or muscle prickling/burning; constipation; difficulty concentrating/muscular weakness; tremor; weight loss.

Stores Affected

- WanaBana apple cinnamon fruit puree pouches are sold nationally and are available through multiple retailers including Amazon, Dollar Tree, and other online outlets.
    - FDA is aware that recalled WanaBana Apple Cinnamon Puree is still on the shelves at several Dollar Tree stores in multiples states. This product should not be available and consumers should not purchase this product.
- Schnucks-brand cinnamon-flavored applesauce pouches and variety pack are sold at Schnucks and Eatwell Markets grocery stores.
- Weis-brand cinnamon applesauce pouches are sold at Weis grocery stores.

Status

Ongoing; updates to this advisory will be provided as they become available.

Recommendation

- Consumers should not eat, sell, or serve recalled WanaBana, Schnucks, or Weis-brand apple cinnamon pouches and should discard them.
- These products have a long shelf life. Consumers should check their homes and discard these products.
- To properly discard the product, consumers and retailers should carefully open the pouch and empty the content into a trash can before discarding the packaging to prevent others from salvaging recalled product from the trash. Clean up any spills after discarding the product then wash your hands.
- Most children have no obvious immediate symptoms of lead exposure. If there's suspicion that a child may have been exposed to lead, parents should talk to their child's healthcare provider about getting a blood test.
- Contact your healthcare provider if you think you may have symptoms of lead toxicity after eating recalled fruit pouches.
- If you or your child have symptoms or exposure to this product, you can also file a complaint or adverse event report (illness or serious allergic reaction).

Current Update

November 30, 2023

On November 30, 2023, Austrofood, along with Wanabana USA, the distributor of WanaBana products in the United States, released a statement that reports that Wanabana has conducted a root cause investigation. Based on this investigation, the firm's leading hypothesis to date is that the cinnamon is the source of the elevated lead levels in the recalled products. The statement released today by Wanabana USA and Austrofood states that the cinnamon used to manufacture the recalled products was supplied by Negocios Asociados Mayoristas S.A., operating as Negasmart, a third-party distribution company located in Ecuador.

The FDA is continuing to work with Ecuadorian authorities to investigate the source of the contamination and to determine if the cinnamon in the recalled products was used in other products or distributed as a raw ingredient to other countries. FDA has confirmed that Negasmart does not import cinnamon directly into the U.S.

As of November 30, 2023, there have been 57 reports of adverse events potentially linked to recalled product submitted to FDA. To date, confirmed complainants are less than 1 to 5 years of age.

The FDA relies on self-reported information submitted by healthcare providers, consumers, and some state partners who submitted an adverse event report to FDA as an initial step in determining if a product is a potential shared source of exposure amongst complainants. Unlike outbreaks of foodborne illnesses that are genetically linked to pathogens, there is no method to link lead exposure to a specific source, which can make establishing a causal relationship complicated.

While our total reports included in this advisory represent complaints that have been reported to FDA, we recognize there are other avenues for reporting of elevated lead levels. For example, through case reporting from the state health departments to CDC which is routinely done for cases of childhood lead exposure. Because these different avenues for reporting represent two different mechanisms of collecting data, we are currently not including them in our advisory. However, we are working with our state partners and CDC to gather and evaluate as much data as possible, while recognizing there are different mechanisms being leveraged.

FDA's investigation is ongoing to determine the point of contamination and whether additional products are linked to illnesses. At this time, FDA has no indication that this issue extends beyond these recalled products, but to further protect public health, FDA is screening incoming shipments of cinnamon from multiple countries for lead contamination. As of November 30, 2023, there have been no screening results that have tested positive for higher levels of lead. Separately, Austrofood CIA LDA's apple cinnamon fruit puree pouch products exported to the U.S. were added to Import Alert 99-42, detention without physical examination of foods due to heavy metal (toxic element) contamination.

FDA will update the advisory as information becomes available.

Adverse Event Overview

Total FDA Adverse Events: 57*
Report Date Ranges: October 17, 2023 – November 28, 2023
States with Adverse Illness Events: AL (1), AR (1), CA (1), CT (1), FL (1), GA (2) IA (1), IL (2), KY (3), LA (4), MA (3), MD (4), MI (3), MO (1), NC (5), NE (1), NH (1), NM (1), NY (8), OH (2), PA (1), SC (2), TN (1), TX (3) VA (1), WA (3)
Product Distribution: Nationwide

**Estimate based on Consumer Complaint and CFSAN Adverse Event Reporting System (CAERS) reports received by the FDA.*