

<b>DATE:</b>	12/11/2023
<b>TO:</b>	Health Alert Network
<b>FROM:</b>	Debra L. Bogen, MD, FAAP, Acting Secretary of Health
<b>SUBJECT:</b>	<b>Update: Call for Cases of Elevated Lead Levels: Applesauce Pouches - December 2023</b>
<b>DISTRIBUTION:</b>	Statewide
<b>LOCATION:</b>	Statewide
<b>STREET ADDRESS:</b>	n/a
<b>COUNTY:</b>	n/a
<b>MUNICIPALITY:</b>	n/a
<b>ZIP CODE:</b>	n/a
<b>This transmission is a “Health Update” that provides updated information regarding an incident or situation; no immediate action necessary.</b>	

**HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, INFECTION CONTROL, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL EMS COUNCILS: PLEASE DISTRIBUTE AS APPROPRIATE; FQHCs: PLEASE DISTRIBUTE AS APPROPRIATE; LOCAL HEALTH JURISDICTIONS: PLEASE DISTRIBUTE AS APPROPRIATE; PROFESSIONAL ORGANIZATIONS: PLEASE DISTRIBUTE TO YOUR MEMBERSHIP**

### Summary

- This is a follow up to [PAHAN-724](#).
- The U.S. Food and Drug Administration (FDA) has identified and recalled certain cinnamon-containing apple purée and applesauce products contaminated with lead, including WanaBana brand apple cinnamon fruit purée pouches, Schnucks brand cinnamon applesauce pouches, and Weis brand cinnamon applesauce pouches. Please refer to the [FDA website](#) for more information.
- These products were nationally distributed, and states in multiple regions, including Pennsylvania, have received the recalled products.
- The Centers for Disease Control and Prevention (CDC) is coordinating with state and local health departments to ascertain information from individuals with higher blood lead levels potentially associated with consuming recalled WanaBana, Schnucks, and Weis brand fruit purée products after November 2022. This is important to understand the scope and magnitude of the outbreak with respect to geography and time. Please refer to the [CDC website](#) for more information.
- **The Pennsylvania Department of Health (PA DOH) asks providers to report individuals with blood lead levels of 3.5 µg/dL or higher detected through venous, capillary or unspecified testing within 3 months after consuming a WanaBana, Schnucks, or Weis brand cinnamon applesauce or apple purée product containing cinnamon after November 2022 to PA DOH by securely emailing the following information to [RA-DHBOE-RESPONSE@pa.gov](mailto:RA-DHBOE-RESPONSE@pa.gov) or by fax: 717-772-6975.**
- PA DOH is also asking individuals to reach out and contact their providers if they suspect they may have elevated blood levels due to consumption of the applesauce so their provider can report it to PA DOH.
- For more information on childhood lead exposure in Pennsylvania, visit [Lead \(pa.gov\)](#) or contact PA DOH at 1-877-PA-HEALTH or by sending a secure email to [RA-DHBOE-RESPONSE@pa.gov](mailto:RA-DHBOE-RESPONSE@pa.gov) if you have any questions.

### Background

Lead exposure can have serious consequences for children's and pregnant persons' health. Lead is ubiquitous in the environment; unfortunately, we cannot see, taste, or smell lead. Lead is much more harmful to children and pregnant persons because it can affect children's developing nervous systems and brains.

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. A statement released 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 U.S. Food and Drug Administration (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 December 1, 2023, there have been 64 reports of adverse events potentially linked to recalled product submitted to [FDA](#). To date, complainants are less than 1 to 5 years of age.

The Centers for Disease Control and Prevention (CDC) is also providing [updates](#) on this investigation. As of December 1, 2023, CDC has received 52 reports from 13 states.

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.

Consumers who have symptoms should contact their healthcare provider to report their symptoms and receive care.

To report a complaint or adverse event (illness or serious allergic reaction), you can

- Call an [FDA Consumer Complaint Coordinator](#) if you wish to speak directly to a person about your problem.
- Complete [an electronic Voluntary MedWatch](#) form online.
- Complete [a paper Voluntary MedWatch](#) form that can be mailed to FDA.

Visit [www.fda.gov/fcic](http://www.fda.gov/fcic) for additional consumer and industry assistance.

## Recommendations

### For healthcare providers:

- Review recall information, including pictures of the specific item being recalled. This information is available on the [FDA website](#).
- Providers should raise awareness about the recalled products among patients or parents and recommend testing, as appropriate.
- Consider blood lead testing for individuals if they consumed these products or are exposed to other potential lead sources.
- The CDC is coordinating with state and local health departments to ascertain information from individuals with higher blood lead levels potentially associated with consuming recalled WanaBana, Schnucks, and Weis brand fruit purée products after November 2022. This is

important to understand the scope and magnitude of the outbreak with respect to geography and time. Please refer to the [CDC website](#) for more information.

- **Providers should report individuals with blood lead levels of 3.5 µg/dL or higher detected through venous, capillary or unspecified testing within 3 months after consuming a WanaBana, Schnucks, or Weis brand cinnamon applesauce or apple purée product containing cinnamon after November 2022 to PA DOH by securely emailing the following information to [RA-DHBOE-RESPONSE@pa.gov](mailto:RA-DHBOE-RESPONSE@pa.gov) or by fax: 717-772-6975.**
  - First and last name
  - Date of birth
  - Address
  - Phone Number
  - Sex
  - Pregnancy status
  - Breastfeeding
  - Race
  - Ethnicity
  - Did the person consume a WanaBana, Schnucks, or Weis brand cinnamon applesauce or apple purée product containing cinnamon after November 2022?
  - Dates and quantity consumed (First and last day consumed, how many per week)
  - Was the person tested for blood lead levels within 3 months of consuming the product?
  - Was the person's blood lead level 3.5 µg/dL or higher?
  - Was a confirmatory venous test conducted?
  - Any immediate symptoms?
  - Are you aware of any known contact the individual has had with other products or materials that might contain lead?
- For additional information regarding the recall, providers can contact the PA DOH by securely sending an email to [RA-DHBOE-RESPONSE@pa.gov](mailto:RA-DHBOE-RESPONSE@pa.gov).
- Laboratories and health care providers are required to report all blood lead test results, regardless of the lead level, for persons under 16 years of age to PA DOH through Pennsylvania's electronic disease surveillance system, PA-NEDSS. Individuals who need a PA-NEDSS account should complete a [Prime Contact Information Form](#) and send the completed form to [PA-NEDSS@pa.gov](mailto:PA-NEDSS@pa.gov).

#### **For parents and consumers:**

- Encourage individuals to dispose the recalled products immediately, get tested if they or their child ate the product, and report previous consumption of the product to the provider if the individual has elevated blood lead levels.

- Consumers should not eat, sell, or serve these recalled products. Consumers should immediately stop using them and return them to the place of purchase for a full refund. Consumers with questions can contact WanaBana at support@wanabanafruits.com, or the Schnucks Customer Care team at 314-994-4400 or 1-800-264-4400, or the Weis Customer Service number at 866-999-9347.
- These products have a long shelf life. Consumers should check their homes and discard these products.
- 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 or your child may have symptoms of lead toxicity after eating recalled fruit pouches.

### Additional resources on childhood lead exposure

- [Lead Poisoning \(pa.gov\)](#)
  - [Elevated Blood Lead Level Resources \(pa.gov\)](#)
  - [Lead Poisoning FAQ \(pa.gov\)](#)
- [Childhood Lead Poisoning Prevention Program | CDC](#)
- PA DOH lead information 1-800-440-LEAD

**For questions, please call your local health department or PA DOH at 1-877-PA-HEALTH (877-724-3258).**

Individuals interested in receiving future PA-HANs can register at <https://ondemand.mir3.com/han-pa-gov/login/>.

Categories of Health Alert messages:

**Health Alert:** conveys the highest level of importance; warrants immediate action or attention.

**Health Advisory:** provides important information for a specific incident or situation; may not require immediate action.

**Health Update:** provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of December 11, 2023, but may be modified in the future.
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