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TO: Hospitals, Local Health Departments, Laboratories, Emergency Rooms, Family Medicine, Pediatrics, Adolescent Medicine, Internal Medicine and Primary Care Providers

FROM: New York State Department of Health (NYSDOH) Bureau of Community Environmental Health and Food Protection (BCEHFP)

HEALTH ADVISORY: RECALLED APPLESAUCE POUCHES POTENTIALLY LINKED TO ELEVATED BLOOD LEAD LEVELS (EBLL) IN CHILDREN

The New York State Department of Health (DOH) is issuing a health advisory to alert providers of the ongoing threat caused by remaining stocks of the recalled products that may remain in people's homes and which may contain extremely high levels of lead. This advisory provides additional local detail to the advisory previously issued by the Centers for Disease Control and Prevention (CDC) with respect to:

- NYS children with elevated blood lead level (EBLL) possibly linked to consumption of applesauce pouches named in the recent FDA recall.
- Need to continue educating families and caregivers that any recalled applesauce pouches remaining in homes, daycares, or other environments involving children need to be immediately discarded according to instructions provided by FDA.
- Need to monitor for elevated blood lead level and provide guidance for children who may have consumed the affected applesauce pouches.

NYSDOH, along with federal partners, is investigating a potential link between ingestion of certain cinnamon containing varieties of applesauce products and elevated blood lead level. Multiple lots of these products have been tested with results indicating that they contain extremely high levels of lead. The implicated manufacturers have initiated voluntary recalls of certain lots of the following products:

- Wanabana brand apple cinnamon fruit puree pouches
- Schnucks brand cinnamon applesauce pouches
- Weis brand cinnamon applesauce pouches

More details about the specific recalled products may be found on the FDA's website: <https://www.fda.gov/food/outbreaks-foodborne-illness/investigation-elevated-lead-levels-applesauce-pouches-november-2023>

Modeling analysis by NYSDOH of the lead levels detected in these products indicate that ingestion of just one pouch per day for a period of weeks to months has the potential to cause elevated blood lead levels (EBLLs) of 5 micrograms per deciliter ($\mu\text{g}/\text{dl}$) or greater in all young children. As little as two pouches per day of such exposure may be sufficient to cause some children to reach a clinical intervention stage involving chelation ($>45 \mu\text{g}/\text{dl}$). While such extremely high elevated blood lead levels have not been reported thus far, the possibility that

this can occur underscores the importance of blood lead testing in young children who have ingested the now recalled apple sauce products.

As of November 16, 2023, there are nine elevated blood lead level cases across New York State associated with the recalled applesauce products as a suspected contributing factor. These cases are not localized to one region and so continued attention to this issue is needed statewide. These cases have presented with blood lead levels ranging from 5 to 13.2 µg/dL.

There is no safe level of lead in children's blood. Any elevated blood lead level identified through a point of care testing device using a capillary blood sample must be referred for a venous confirmatory test analyzed using complex laboratory testing methods such as Inductively Coupled Plasma Mass Spectrometry (ICP-MS) and Graphite Furnace Atomic Absorption Spectroscopy (GFAAS).

Most children with an elevated blood lead level have no obvious immediate symptoms. Lead toxicity primarily targets the central nervous system. Because of their developing nervous systems, children are more vulnerable to the effects of lead exposure than adults. Even low levels of lead in children's blood have been linked to life-long learning, behavioral, and cognitive deficiencies. Acute lead poisoning, observed in cases with extremely high blood lead levels, may present with anemia, abdominal pain, weakness, and severe neurological symptoms (seizures, encephalopathy, and coma).

Providers should be vigilant in screening for cases of elevated blood lead level related to children who have ingested products involved in the applesauce recall. Recommendations include:

- 1) Any blood lead test result of greater than or equal to 3.5 µg/dL identified through a point of care testing device (such as a LeadCare machine) should trigger further discussion with and questioning of the child's parent or guardian. Parents/guardians should be educated about the products associated with the recall and questioned about any past consumption of the affected products.
- 2) Children with a BLL greater than or equal to 3.5 µg/dL from point of care screening whose parents/guardians report consumption of affected applesauce products should be referred for a venous confirmatory test. *Please note that for BLL results between 3.5 and 5 µg/dL where use of the affected product is not reported, venous confirmatory testing is not necessary and providers should follow the standard blood lead testing guidance, which can be found on the NYSDOH website: https://www.health.ny.gov/environmental/lead/health_care_providers/.*
- 3) Any family reporting usage of the affected applesauce products should be instructed to discontinue use and to discard any unused product. Additionally, they should be encouraged to obtain a blood lead test for any children who have consumed the products. While the main focus is currently on very young children, it is important to recognize that older children and teens may have consumed the recalled products and be at risk for elevated blood lead level and lead toxicity. Regardless of age, individuals reporting consumption of any recalled product should obtain a blood lead test.

For More Information

- NYSDOH
 - [Childhood Lead Poisoning Prevention](#)
 - [Regional Lead Resource Centers](#)

- FDA
 - [Investigation of Elevated Lead Levels: Applesauce Pouches \(November 2023\)](#)
 - [MedWatch Online Voluntary Reporting Form](#)
 - [MedWatch Consumer Voluntary Reporting Form](#)
 - [Consumer Complaint Coordinators](#)
- CDC/ATSDR
 - CDC HAN, Nov 13, 2023: <https://emergency.cdc.gov/han/2023/han00500.asp>
 - [Childhood Lead Poisoning Prevention Program](#)
 - [Guidelines and Recommendations](#)
 - [Testing Children for Lead Poisoning](#)
 - [Blood Lead Levels in Children](#)
 - [Toxicological Profile for Lead](#)
 - [Lead ToxFAQs](#)
- America's Poison Centers
 - [U.S. Poison Centers](#)
- Pediatric Environmental Health Specialty Units
 - [About PEHSU / Find an Expert](#)
 - [Recommendations on Management of Childhood Lead Exposure](#)
- American College of Medical Toxicology
 - [About ACMT](#)