January 30, 2019

The Honorable Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Gottlieb:

Consumer Reports, an independent, nonprofit organization that works side by side with consumers to create a fairer, safer, and healthier world, writes regarding our recently completed testing of fruit juices for elements commonly known as "heavy metals," including cadmium, lead, inorganic arsenic and mercury. The article is posted on our site, CR.org.

Based on our findings, we urge the Food and Drug Administration (FDA) to immediately finalize the action level of 10 ppb for inorganic arsenic in apple juice that the agency proposed in 2013. Furthermore, on the basis of what our new testing shows is achievable, we urge the FDA to set a 1 ppb limit for lead and cadmium and rapidly develop a stronger, broader limit for inorganic arsenic of 3 ppb, in all fruit juices affected by heavy metal contamination. These limits should come in the form of a mandatory standard, or, at a minimum, an action level. FDA should set a long-term goal of having no measurable amounts of heavy metals in fruit juice.

As the FDA is aware, exposure to even small amounts of these elements may, over time, increase the risk of several serious health problems, including those involving carcinogenic, cognitive, and reproductive effects. Babies and young children are the most at risk, particularly given the potential harms of heavy metal exposure on developing brains, in the form of lower IQ and behavior problems. Young children frequently consume fruit juice. More than 80 percent of parents of children age three and under give their children fruit juice at least sometimes, according to a recent national Consumer Reports survey of 3,002 parents. In 74 percent of those cases, the children drink juice once a day or more.

As we report in a major story published today, Consumer Reports' food safety team analyzed 45 juices for their heavy metal content, including four types: apple (22), fruit juice blends (13), grape (7), and pear (3). Our findings, based on the testing and risk assessment described in the methodology enclosed, include the following:

- Every product had measurable levels of at least one of these heavy metals: cadmium inorganic arsenic, lead, or mercury.

- Twenty-one (47 percent) of the 45 juices had concerning levels of inorganic arsenic, lead, and/or cadmium. (None contained concerning levels of mercury.)

- Seven of those 21 juices could harm children who drink 4 ounces (½ cup) or more a day; nine more of the 21 pose risks to children at 8 ounces (1 cup) or more a day.

- Five of the products with elevated heavy metal levels are juice boxes or pouches ranging from 4 to 6.75 ounces. These pose a risk to a child who drinks more than one box or pouch per day.

- Ten of the juices pose a risk to adults: five of them at 4 ounces or more a day, and five more of the 10 at 8 ounces or more a day.

- Grape juice and juice blends had the highest average heavy metal levels. Two of these products exceeded the FDA standard for lead in bottled water of 5 ppb.

- Juice brands marketed for children did not fare better or worse than other juices.

- Organic juices did not have lower levels of heavy metals than conventional ones.

We are concerned that the FDA lacks adequate limits on heavy metals in children's food, including fruit juice. With the agency's own data and the work of Consumer Reports and other public interest groups in mind, it is critically important for the FDA to take additional steps to protect public health. We urge the FDA to set a goal of having no measurable amounts of cadmium, lead, mercury, or inorganic arsenic in baby and children's food, including fruit juices—and to use the most sensitive testing methods to determine the presence of those elements.

As steps along the way to achieve this goal, we urge the FDA take the following actions to limit heavy metals in fruit juice:

- **Finalize the proposed inorganic arsenic apple juice action level of 10 ppb.** The FDA had indicated that by the end of 2018, it would finalize its 2013 proposed action level limiting inorganic arsenic in apple juice to 10 ppb, which is the same as the federal arsenic drinking water standard. Although most of the juices in the current CR test meet the proposed action level, which represents a significant improvement over our 2011 test results, one product still exceeded the proposed level by 50 percent, underlining the need to have a final FDA action level in place as soon as possible.

- **Establish a limit for lead in fruit juice of 1 ppb.** It is now well established that lead poses health risks even at very low levels, and exposure is cumulative. Although the FDA requires lead in bottled water to be no greater than 5 ppb, it lacks an adequate limit for lead in fruit juice, merely suggesting in guidance that manufacturers should seek to keep lead in juice to a level no greater than 50 ppb. We have previously proposed that the FDA at least limit lead in fruit juice to the same level as the bottled water standard, and in our most recent tests, two grape juice-containing products exceeded the bottled water

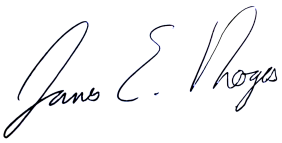
standard. However, a majority of products performed much better, exhibiting lead levels at or below 1 ppb, the maximum level that the American Academy of Pediatrics advocates for school drinking water fountains. We therefore urge the FDA to establish a mandatory standard, or at a minimum an action level, of 1 ppb for lead in all fruit juices affected by heavy metal contamination.

- **Establish a limit for cadmium in fruit juice of 1 ppb.** The risks of cadmium are similar to those of lead. More than 90 percent of the juice samples in our test exhibited less than 1 ppb of cadmium, indicating that 1 ppb is achievable. We therefore urge the FDA to establish a limit of 1 ppb for cadmium in all fruit juices affected by heavy metal contamination—again, in the form of a mandatory standard or, at a minimum, an action level—while studying its effects and the potential for additional regulatory action.

- **Establish a new limit for inorganic arsenic in all affected juice products of 3 ppb.** Arsenic poses developmental and reproductive risks and is a powerful carcinogen. The FDA's proposed inorganic arsenic action level covers apple juice only. However, our tests also found inorganic arsenic in grape and pear juice and juice blends. The FDA should limit inorganic arsenic in all fruit juices affected by heavy metal contamination to the lowest possible achievable level. In our tests, 58 percent of samples were below 3 ppb of inorganic arsenic, indicating such a limit is achievable to meet. We therefore urge the FDA to set a new 3 ppb limit for inorganic arsenic that is applicable to all affected types of juice, in the form of a mandatory standard or, at a minimum, an action level.

We appreciate your consideration of these critical issues, and kindly request a response to this letter at your earliest convenience. Consumer Reports looks forward to working with you to prevent contamination, reduce levels of heavy metals in food and drinks, and limit the risk of food safety harm to consumers nationwide.

Sincerely,



Jean Halloran
Director of Food Policy Initiatives

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Enclosures: *Arsenic and Lead Are In Your Fruit Juice: What You Need to Know*,
Consumer Reports Methodology for Testing Heavy Metals in Fruit Juice