April 17, 2019

Norman E. Sharpless, M.D., Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Acting Commissioner Sharpless:

Consumer Reports, an independent, nonprofit member organization that works side by side with consumers to create a fairer, safer, and healthier world, writes regarding our recently completed investigation of arsenic in bottled water, which raises important safety concerns. The article is posted on our site, CR.org.

Arsenic poses health risks even at very low levels of exposure, including the risk of IQ loss in children and the risk of cancer in adults.[1] Based on our findings, we urge the Food and Drug Administration (FDA) to take a number of steps to protect the public from potential arsenic exposure via bottled water. First, we urge you to revise downward the current FDA bottled water arsenic standard, from 10 to 3 parts per billion (ppb). Second, we urge the FDA to improve enforcement of its bottled water standards by inspecting bottlers more frequently, testing the bottled water produced for arsenic and other contaminants, and requiring the recall of products that violate standards. Third, we urge you to exercise greater vigilance on imports, particularly with regard to products where you have identified violations of standards in the past. We explain these recommendations in greater detail below.

Consumers are increasingly buying bottled water, often due to fears about the safety of municipal water supplies. Sales of bottled water rose nearly 20 percent between 2015, when the scandal broke about Flint, Michigan's contaminated water, and 2018, according to the International Bottled Water Association.[2] Bottled water should be as safe or safer than municipal water, given that consumers pay a premium for it.

Our investigation found, however, that at least one type of bottled water, Penafiel, a Keurig Dr Pepper brand, produced in Mexico, exceeded the FDA standard for arsenic, registering more than 17 ppb in our tests. We are calling on the company to recall this product because it violates the

[1] https://www.des.nh.gov/organization/commissioner/pip/publications/documents/r-wd-18-20.pdf, https://www.niehs.nih.gov/health/topics/agents/arsenic/index.cfm, https://www.mailman.columbia.edu/public-health-now/news/us-schoolchildren-exposed-arsenic-well-water-have-lower-iq-scores

[2] https://issuu.com/ibwa/docs/ibwa_2018progressreport, https://www.bottledwater.org/public/BMC2017_BWR_StatsArticle.pdf

FDA limit and therefore poses a significant public health risk. If they fail to implement a recall, the FDA should require them to do so.

Another brand, Starkey's, produced in Idaho and sold at Whole Foods, tested very close to the FDA limit, with three samples above 9 ppb, and one at 10.1 ppb. A review of about 130 company testing reports and public records—representing about half of active bottlers we identified from publicly available sources—found that six brands reported 3 ppb or higher of arsenic. On the other hand, the same review showed that arsenic is non-detectable in the bottled water produced by many companies. Arsenic is not always present in water, but if it is, it can be almost entirely removed by filtration. It is thus an avoidable risk.

We therefore urge the FDA to:

1. **Revise downward the current standard for arsenic in bottled water from 10 to 3 ppb.** The U.S. Environmental Protection Agency standard for drinking water is 10 ppb. However, EPA originally proposed a standard of 3 ppb, ultimately setting it at 10 ppb, in part due to feasibility of implementation in municipal water supplies. New Jersey has a tougher drinking water standard of 5 ppb.

   The FDA can and should set the bottled water standard below the federal drinking water standard. It already does so for lead, where the federal drinking water standard is 15 ppb but the bottled water standard is 5 ppb. The U.S. National Toxicology Program classifies arsenic and inorganic arsenic compounds as "known to be human carcinogens." The International Agency for Research on Cancer (IARC), part of the World Health Organization (WHO), classifies arsenic and inorganic arsenic compounds as "carcinogenic to humans", based on evidence from human studies that it can cause cancer of the lung, bladder, and skin. IARC also notes possible links between exposure to arsenic in drinking water and cancers of the kidney, liver, and prostate, although the evidence for these is not as strong.[3]

   Bottled water is now the number one packaged beverage sold in the United States by volume.[4] Arsenic can be mostly filtered out of bottled water and according to company test data, more than 100 brands of bottled water are already reporting undetectable levels. While it would be best for public health if consumers had no exposure to arsenic in bottled water, a standard of 3 ppb is now clearly feasible and would provide important protection for Americans from cancer risks and developmental problems.

2. **Increase and improve bottler inspections and enforcement of standards, including through recalls.** Based on information we received in response to a Freedom of Information Act request, the FDA inspected just 211 bottlers in 2018, down from 371 in 2010. The FDA should increase the number of inspections it currently conducts. Specifically, the agency should utilize records submitted to the state of California and

[3] https://www.cancer.org/cancer/cancer-causes/arsenic.html

[4] https://issuu.com/ibwa/docs/ibwa_2018progressreport

other state agency data to help focus inspections on facilities where arsenic levels are most concerning.

In addition, it is our understanding that the focus of inspections is Good Manufacturing Practices, such as proper sanitation. The agency also should collect samples of bottled water at facilities and analyze them for key toxic elements, including arsenic. If violations are found, penalties should be imposed and recalls required. The FDA checks that companies are keeping records of contaminant levels, but FDA inspection reports show that in certain cases such records were missing. To improve the effectiveness of inspections, the FDA should recheck companies that lacked records, to ensure recordkeeping deficiencies have been remedied.

3. **Increase policing of imported bottled water, including testing of imported brands.** Consumer Reports was able to purchase Penafiel bottled water on the Internet, and it is available at Walmart and for purchase online from Target. Penafiel is subject to an Import Alert, which should ensure that its product gets special scrutiny due to violations having been found in the past. However, when CR tested that water for arsenic, the samples exceeded the FDA arsenic standard. The FDA should ensure that imported brands are tested for toxic substances, and that products subject to an Import Alert are closely monitored.

We appreciate your consideration of our findings and recommendations, 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 toxic elements in food and drinks, and limit the risk of food safety harm to consumers nationwide.

Sincerely,

Jean Halloran
Director, Food Policy Initiatives

cc: Frank Yiannas, FDA Deputy Commissioner for Food Policy and Response