



Consumer Federation of America

February 14, 2024

Commissioner Robert Califf
U.S. Food and Drug Administration

SENT VIA EMAIL

Re: Safety determination of cola-type beverages with caffeine levels exceeding 0.02 percent

Dear Commissioner Califf:

Consumer Federation of America writes to urge you to clarify food manufacturers' duty to evaluate the safety of cola-type beverages with caffeine levels exceeding 0.02 percent, and to take appropriate enforcement actions against manufacturers of unsafe products, including the Panera Bread restaurant chain's "Charged Lemonade."

The subject of two wrongful death lawsuits, until recently a large (30 ounce) cup of Panera's Charged Lemonade contained 390 mg of caffeine, with free refills available. Notably, FDA's website recommends that "healthy adults" consume no more than 400 mg of caffeine in an entire day.¹ Panera has since reformulated the beverage to contain less caffeine, but FDA's silence suggests that the agency may consider similarly caffeinated "cola-type" beverages to comply with federal regulatory requirements.

Such a permissive regulatory interpretation lacks support. While caffeine is naturally occurring in some foods and beverages like chocolate and coffee, it is a "food additive" in "cola-type beverages" like the Panera Charged Lemonade. FDA rules set the upper limit for caffeine in these beverages at 0.02%. At this concentration, caffeine "is generally recognized as safe ["GRAS"] when used in cola-type beverages in accordance with good manufacturing practice."² However, Panera's Charged Lemonade contained roughly 0.04% caffeine, or twice the concentration prescribed in the rules.

As FDA explained in a 2009 warning letter, "use of caffeine" in beverages at "higher use levels" than the 0.02% prescribed by the rules requires:

"both evidence of safety (the 'technical element' of the GRAS standard) and a basis to conclude that this evidence is generally known and accepted by qualified experts. The technical element of the GRAS standard requires that the information about the substance establish that the intended use of the substance is safe, i.e., that there is a reasonable certainty in the

¹ See Carlie Procell. "Lawsuits say Panera's Charged Lemonade can cause cardiac arrest: Caffeine intake in graphics." *USA Today*, Dec. 12, 2023, <https://www.usatoday.com/story/graphics/2023/12/12/panera-charged-lemonade-caffeine-deaths/71851706007/>.

² 21 C.F.R. § 182.1180.

minds of competent scientists that the substance is not harmful under its intended conditions of use. In addition, the data and information to establish the technical element must be generally available, and there must be a basis to conclude that there is a consensus among qualified experts about the safety of the substance for its intended use.”

Panera’s Charged Lemonade does not appear to meet either of these elements.

Most troubling, the drink appears to have caused two deaths and at least one other serious adverse event.³ But even absent these events, the drink implicates obvious safety concerns. Packing twice the “normal” concentration of caffeine for a “cola-type” beverage in a “lemonade,” a beverage that does not customarily contain any caffeine, logically entails a high likelihood that many consumers—including those more vulnerable to ill health effects—will inadvertently consume more caffeine than intended. Indeed, various anecdotal accounts online support this notion. Second, the various studies raising concerns about highly caffeinated energy drinks and other sugar-sweetened beverages belies the notion that “there is a consensus among qualified experts about the safety of the substance for its intended use.”⁴ In fact, health officials at a large public university recently felt moved to specifically warn students about Panera Charged lemonade.⁵

Just as FDA has demanded manufacturers of alcoholic beverages containing caffeine, and of caffeine in powdered form, to demonstrate the “rationale, and supporting data and information, for concluding that your use of caffeine . . . is GRAS or prior sanctioned,” so too should it demand that information from Panera. Assuming that the company has not assembled an adequate evidentiary basis for the Charged Lemonade’s safety, FDA should make clear that the beverage, as originally formulated with 0.04% caffeine, is not GRAS. Doing so will send an important message to manufacturers of other highly caffeinated beverages.

Failing to demand safety information from Panera sends the implicit message that other companies may push the boundaries towards unsafe levels of caffeine in drinks without fear of regulatory consequences. According to one recent study, caffeine serves to “enhance desirable tastes, such as sweetness and saltiness, in beverages by modifying neurological pathways.”⁶ Indeed,

³ Greg Wehner, *Third Lawsuit Against Panera Claims Caffeinated ‘Charged Lemonade’ Caused ‘Permanent Cardiac Injuries’*, Fox Bus. (Jan. 18 2024, 9:22 PM), <https://www.foxbusiness.com/markets/third-lawsuit-against-panera-claims-caffeinated-charged-lemonade-caused-permanent-cardiac-injuries>.

⁴ See Vincenzo de Sanctis, et al., *Caffeinated Energy Drink Consumption Among Adolescents and Potential Health Consequences Associated with Their Use: A Significant Public Health Hazard*, 88 ACTA BIOMED 222, 222–23, 228 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6166148/>; Jennifer L. Pomeranz, et al., *Energy Drinks: An Emerging Public Health Hazard for Youth*, 34 J. PUB. HEALTH POL’Y 254, 254–271 (2013), <https://link.springer.com/article/10.1057/jphp.2013.6>.

⁵ Madison Maronge, *Don’t Overcharge on Panera’s Caffeine-Filled Charged Lemonades, LSU Health Director Urges Students*, REVEILLE (Dec. 7, 2023), https://www.lsureveille.com/news/what-do-dietitians-say-about-paneras-charged-lemonades/article_72e88cd2-8ef8-11ee-982d-075271f00a74.html.

⁶ See Ann-Marie A. Allison & Edgar Chambers IV, *The Importance of Caffeine as a Flavor Component in Beverages*, 15 J. SENSORY STUD. 449, 449 (2007), <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1745-459X.2000.tb00282.x#:~:text=Caffeine%20contributes%20to%20the%20flavor,beverages%20by%20modifying%20neurological%20pathways>; see also Nicola J. Richardson, et al., *Conditioned Flavour Preferences Reinforced by Caffeine Consumed After Lunch*, 30 PSYCH. & BEHAV. 257, 257 (1996), <https://www.sciencedirect.com/science/article/abs/pii/S0031938495022031?via%3Dihub>.

caffeine's reinforcing properties, its capacity to "induce flavor preference,"⁷ and its importance as a flavor component in beverages,⁸ create powerful incentives for companies to seek an edge in the market by using higher levels of caffeine.

FDA should not let these incentives go unchecked. The law requires food and beverage manufacturers to make a GRAS safety determination when departing from the caffeine levels prescribed by federal rules. FDA should hold to account Panera and any other companies selling highly caffeinated "cola-type" beverages. Doing so will send an important message, and ultimately protect consumers.

Thank you for your consideration.

Sincerely,

Thomas Gremillion
Director of Food Policy
Consumer Federation of America

CC:

FDA Deputy Commissioner for Human Foods Jim Jones
Director (Acting) of FDA Office of Food Additive Safety Dr. Kristi Muldoon-Jacobs,

⁷ Sergi Ferré, *An Update on the Mechanisms of the Psychostimulant Effects of Caffeine*, 105 J. NEUROCHEMISTRY 1067, 1068 (2008), <https://onlinelibrary.wiley.com/doi/epdf/10.1111/j.1471-4159.2007.05196.x>.

⁸ Ann-Marie A. Allison & Edgar Chambers IV, *supra* note 7.