



March 15, 2020

Dr. Susan T. Mayne  
Director, Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
Department of Health and Human Services  
Silver Spring, MD 20993

Dear Dr. Mayne:

The Center for Science in the Public Interest (CSPI)<sup>1</sup> and Consumer Federation of America (CFA)<sup>2</sup> write to urge the Food and Drug Administration (FDA) to take immediate enforcement action against Molson Coors Beverage Company, the manufacturer of Vizzy Hard Seltzer, and any other manufacturers making claims on FDA-regulated<sup>3</sup> alcoholic beverages based on the presence of nutrients added through fortification.

The labeling of Vizzy Hard Seltzer, made by Molson Coors, features prominent claims declaring that the beverage is made with vitamin C. These claims are in clear violation of the FDA's fortification policy, which states that: "[FDA does] not consider it appropriate to add vitamins and minerals to alcoholic beverages."<sup>4</sup> The claims are also misleading in violation of the Federal Food, Drug, and Cosmetic Act (FFDCA)<sup>5</sup> because they suggest that Vizzy is a healthful source of nutrients, obscuring the fact that alcoholic beverages provide empty calories,<sup>6</sup> are associated with serious health conditions,<sup>7</sup> and can impair the body's metabolism of nutrients.<sup>8</sup> These misleading claims make Vizzy misbranded under the FFDCA.

In this letter, we call on the FDA to take action against this manufacturer and to formally prohibit nutrient content claims on alcoholic beverages. Such actions would prevent consumers from being misled about the nutritional properties of alcoholic beverages and encourage consumers to select healthful sources of nutrients as part of a well-rounded diet.

#### **I. Alcoholic beverages are not healthful sources of nutrients.**

Ethyl alcohol [or ethanol], which is the alcohol in alcoholic drinks, contains seven calories per gram. However, alcohol is not an essential nutrient. According to a 2004 report funded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA):

Alcoholic beverages primarily consist of water, pure alcohol (chemically known as ethanol), and variable amounts of sugars (i.e., carbohydrates); their content of other nutrients (e.g., protein, vitamins, or minerals) is usually negligible. (Because they provide almost no nutrients, alcoholic beverages are considered "empty calories").<sup>9</sup>

Because alcoholic beverages “supply calories but few nutrients,” the 2020-2025 Dietary Guidelines for Americans (DGA) encourages “[a]dults who choose to drink . . . to limit daily intakes . . . so as not to exceed daily calorie limits,” and cautions that, in general, “drinking less is better for health than drinking more.”<sup>10</sup> The DGA further notes that, “among those who drink, alcoholic beverages, alone, account for most of the calories that remain after meeting food group recommendations in nutrient-dense forms.”<sup>11</sup>

Outside of its contribution to excess calories in the diet, alcohol consumption is also associated with a range of negative health outcomes. The DGA states that:

Evidence indicates that, among those who drink, higher average alcohol consumption is associated with an increased risk of death from all causes compared with lower average alcohol consumption. Alcohol misuse or consuming alcohol in excess of recommendations increases risk of several other conditions such as liver disease, cardiovascular disease, injuries, and alcohol use disorders [...] Emerging evidence suggests that even drinking within the recommended limits may increase the overall risk of death from various causes, such as from several types of cancer and some forms of cardiovascular disease.<sup>12</sup>

Over the long-term, consuming excess alcohol can also impair the body’s ability to digest and utilize nutrients.<sup>13</sup>

## **II. Fortification of alcoholic beverages is inconsistent with FDA’s fortification policy.**

FDA promulgated its fortification policy “to establish a uniform set of principles that will serve as a model for the rational addition of nutrients to foods.”<sup>14</sup> FDA describes this purpose in the preamble to the final policy statement:

The fundamental premise underlying these guidelines is that food fortification should provide consumers with a reasonable benefit without contributing to nutritional imbalance in the diet and without misleading consumers into believing that the consumption of the fortified food per se will ensure a complete or nutritionally sound diet.<sup>15</sup>

As a result, FDA cautions that “[n]ot every food is an appropriate carrier for additional nutrients, and unwarranted fortification of numerous foods could mislead consumers into believing such fortification is necessary or appropriate and could lead to public health problems.”<sup>16</sup> “Random” fortifications “could also result in deceptive or misleading claims for certain foods.”<sup>17</sup> Consequently, the fortification of “snack foods such as candies and carbonated beverages” is not consistent with the fortification policy.<sup>18</sup>

More specifically, in a separate guidance document entitled “Questions and Answers on FDA’s Fortification Policy: Guidance for Industry,” FDA states:

#### **B4. Is it appropriate to add vitamins and minerals to alcoholic beverages?**

No. Under our fortification policy, we do not consider it appropriate to add vitamins and minerals to alcoholic beverages.<sup>19</sup>

This determination is consistent with the FDA's definition of "snack foods," a category that includes "carbonated beverages" and "foods that are not naturally nutrient dense."<sup>20</sup> FDA-regulated alcoholic beverages, such as hard seltzers and ciders made with fermented sugar, *are* "carbonated beverages," and, as noted above, alcoholic beverages provide "empty calories."<sup>21</sup>

### **III. FDA-regulated alcoholic beverages that make claims based on fortification are "misbranded" under 21 U.S.C. § 343(a).**

FDA has regulatory authority over alcoholic beverages under its broad authority to regulate "foods," which the FFDCa defines as "articles used for food or drink..."<sup>22</sup> This authority overlaps with the Alcohol and Tobacco Tax and Trade Bureau's (TTB) authority over "distilled spirits, certain wines, and malt beverages" pursuant to the Federal Alcohol Administration Act (FAA Act).<sup>23</sup> Based on a Memorandum of Understanding between the two agencies, TTB "is responsible for the promulgation and enforcement of regulations with respect to the labeling of" alcoholic beverages covered by the FAA Act.<sup>24</sup> However, where an alcoholic beverage is not covered by the FAA Act, the product is subject to the labeling requirements of the FFDCa.<sup>25</sup> Certain beers, as well as sugar-based hard ciders and seltzers, do not meet the definitions of "distilled spirits, wines, and malt beverage products" and, therefore, are subject to the FFDCa.<sup>26</sup>

The FFDCa, 21 U.S.C. § 343(a), provides that a food is misbranded if "its labeling is false or misleading in any particular."<sup>27</sup> Although foods bearing claims based on a nutrient addition that is inconsistent with the fortification policy are not *per se* false and misleading,<sup>28</sup> the FDA has made clear that such fortifications "could . . . result in deceptive or misleading claims for certain foods"<sup>29</sup> and that the agency "will continue to determine in specific situations whether labeling claims about nutrient additions may be false or misleading."<sup>30</sup>

For the following reason, among others, claims on alcoholic beverages based on fortification are misleading, in violation of the FFDCa:

- (1) Alcoholic beverages provide empty calories, and the DGA encourages consumers "to limit daily intakes . . . so as not to exceed daily calorie limits."<sup>31</sup> Alcoholic beverages, moreover, are "not a component of the USDA Dietary Patterns."<sup>32</sup> Claims based on added nutrients misleadingly suggest that alcoholic beverages can be part of a healthy diet and are thus contrary to the recommendations of the DGA.
- (2) Alcohol also is uniquely associated with a wide range of severe health conditions. Indeed, according to the DGA, "evidence indicates that, among those who drink, higher average alcohol consumption is associated with an increased risk of death from all causes."<sup>33</sup> Claims on alcoholic beverages based on added nutrients misleadingly obscure alcohol's harmful effects on health.

- (3) Excess alcohol consumption, over the long-term, actually impairs the body's ability to digest and utilize nutrients.<sup>34</sup> Fortification claims implying that alcoholic beverages are a healthful source of nutrients are therefore misleading.

For these reasons, alcoholic beverages that make claims relating to fortification are misbranded pursuant to 21 U.S.C. § 343(a).<sup>35</sup>

#### **IV. Vizzy Hard Seltzer, specifically, is misbranded under the FFDCA.**

Vizzy Hard Seltzer, for the reasons discussed above, falls under FDA's regulatory authority. The drink contains 18 mg, or 20% of the Recommended Dietary Intake (RDI), of vitamin C per serving (see Nutrition Facts label in Appendix). The product's labeling makes the claim: "with antioxidant vitamin C from acerola superfruit" (*see* Appendix). This claim appears prominently on Vizzy's cans, cardboard packaging, and other marketing materials.

The addition of vitamin C is a feature that is intended to distinguish the product from other hard seltzers and is its primary selling point. The product's website states: "Another hard seltzer? Yeah, but we've got antioxidant vitamin C."<sup>36</sup> Another advertisement touts Vizzy as "First hard seltzer made with antioxidant vitamin C from acerola superfruit" (*see* Appendix). Molson Coors is clearly aiming to position Vizzy as a healthier hard seltzer.

FDA's fortification policy defines "fortification" as "the addition of a vitamin, mineral, or protein to a food."<sup>37</sup> The use of dried acerola juice in Vizzy is fortification because this ingredient is used to add vitamin C.

Vizzy's claim "with antioxidant vitamin C from acerola superfruit" makes clear that the purpose of adding dried acerola juice is to add vitamin C. Though it is possible that dried acerola juice also plays a preservative role by supplying vitamin C,<sup>38</sup> the use of the terms "antioxidant" and "superfruit" in the marketing of Vizzy suggests that the use of vitamin C is not added for its functional properties, but rather to indicate the drink is a healthful and nutritious source of the vitamin for marketing purposes. The ingredient is also not apparently used as a sweetener, as it appears in very low quantities, or as a flavoring, as it is not included in the "hint of" statements characterizing the products' flavors (*e.g.*, "hint of pineapple mango").

In sum, because Vizzy makes claims based on the presence of nutrients added through fortification, it is misbranded.

#### **V. Vizzy's claim is not saved by other FDA regulations.**

The FFDCA permits, and FDA regulations authorize, certain "nutrient content claims."<sup>39</sup> However, Vizzy's claims do not qualify as such, and, even if they did, they would still be unlawful because they are misleading.

First, Vizzy's vitamin C claim is not a defined nutrient content claim. Under the Nutrition Labeling and Education Act (NLEA), which amended the FFDCA, Congress prohibited labeling claims that "characterize[] the level of any nutrient" (that is, nutrient content claims) unless the

claims “use[] terms which are defined in regulations” by the FDA.<sup>40</sup> Through regulations, the FDA has defined numerous nutrient content claims, such as “high” claims (e.g., “high in vitamin C”) and “good source” claims (e.g., “good source of vitamin C”).<sup>41</sup>

The FDA also authorizes certain synonyms for the defined nutrient content claims. For example, manufacturers may use the terms “provides” and “contains” in lieu of “good source.”<sup>42</sup> As the FDA has made clear, manufacturers are “prohibited” from using “unauthorized synonyms” of nutrient content claims.<sup>43</sup> Vizzy’s claim is most akin to a “good source” claim, which indicates that the product has at least 10 percent of the RDI of the referenced nutrient, because “with” has a similar definition as “contains.”<sup>44</sup> But, “with” is not an authorized synonym for “good source.” For this reason, Vizzy’s claim is, in fact, expressly prohibited by the FFDCA. Indeed, this is a further reason why Vizzy is misbranded.<sup>45</sup>

Second, and more importantly, even if Vizzy’s claim was a defined nutrient content claim, the product must still comply with the FFDCA’s prohibition on false and misleading labeling. The FDA has never suggested that, by issuing regulations defining certain nutrient content claims, it abandoned its authority under 21 U.S.C. § 343(a) to determine on a case-by-case basis that claims meeting those definitions are false and misleading. Indeed, FDA has consistently maintained that “any labeling claims or statements about the addition of a vitamin . . . to a food shall be made *only if* . . . [t]he claim or statement is not false or misleading . . . *and* . . . [t]he claim or statement complies with any applicable regulations such as those in the food labeling regulations (21 CFR part 101).”<sup>46</sup> FDA has further stated that it “will continue to determine in specific situations whether labeling claims about nutrient additions may be false or misleading in the case of foods fortified in ways not provided for in [the fortification] guidelines.”<sup>47</sup>

FDA’s position is consistent with the applicable statutes. As FDA has noted, even before the passage of the NLEA, it had the authority to “regulate[] deceptive nutrient content claims” pursuant to 21 U.S.C. § 343(a).<sup>48</sup> The NLEA was intended to “strengthen[]” the FDA’s existing authority under 21 U.S.C. § 343(a) by giving the agency “[c]lear” authority to issue regulations on an across-the-board basis “limiting the use of claims that . . . characterize the level of a nutrient.”<sup>49</sup> Thus, nothing in the NLEA weakened FDA’s authority under 21 U.S.C. § 343(a).

## **VI. FDA should take enforcement action against Molson Coors’ misbranded Vizzy Hard Seltzer Product.**

For all of the reasons above, Vizzy is misbranded. Based on the above, CSPI and CFA respectfully urge FDA to take enforcement action against Molson Coors for making misleading claims in the labeling and marketing of Vizzy Hard Seltzer, and against any other manufacturers of alcoholic beverages making claims, implied or explicit, based on fortification.

Claims such as “made with antioxidant vitamin C” convey healthfulness and are misleading on alcoholic beverages given their empty calories, association with serious health conditions, and anti-nutrient properties. Such claims may mislead consumers to believe alcoholic beverages are healthful sources of nutrients.

Taking enforcement against such claims should be a priority for the agency because of the harm these products pose to the public. These claims harm public health by hindering consumers' ability to make sound and healthful decisions about alcohol consumption and to select proper sources of nutrients as a part of a well-rounded diet.

In addition, we encourage the agency to move expeditiously to issue regulations formally prohibiting nutrient content claims on FDA-regulated alcoholic beverages, regardless of whether these claims are based on nutrients added through fortification. This should be made explicit both in FDA's fortification policy at 21 C.F.R. § 104.20 and in FDA's regulations regarding nutrient content claims at 21 C.F.R. § 101.13.<sup>50</sup>

Alcohol is never a good way to obtain nutrients. If these claims are not expressly prohibited, more manufacturers may attempt to market their alcoholic beverages as healthful sources of nutrients, misleading consumers about these drinks, which are not healthy.

Thank you for considering this enforcement request.

Sincerely,

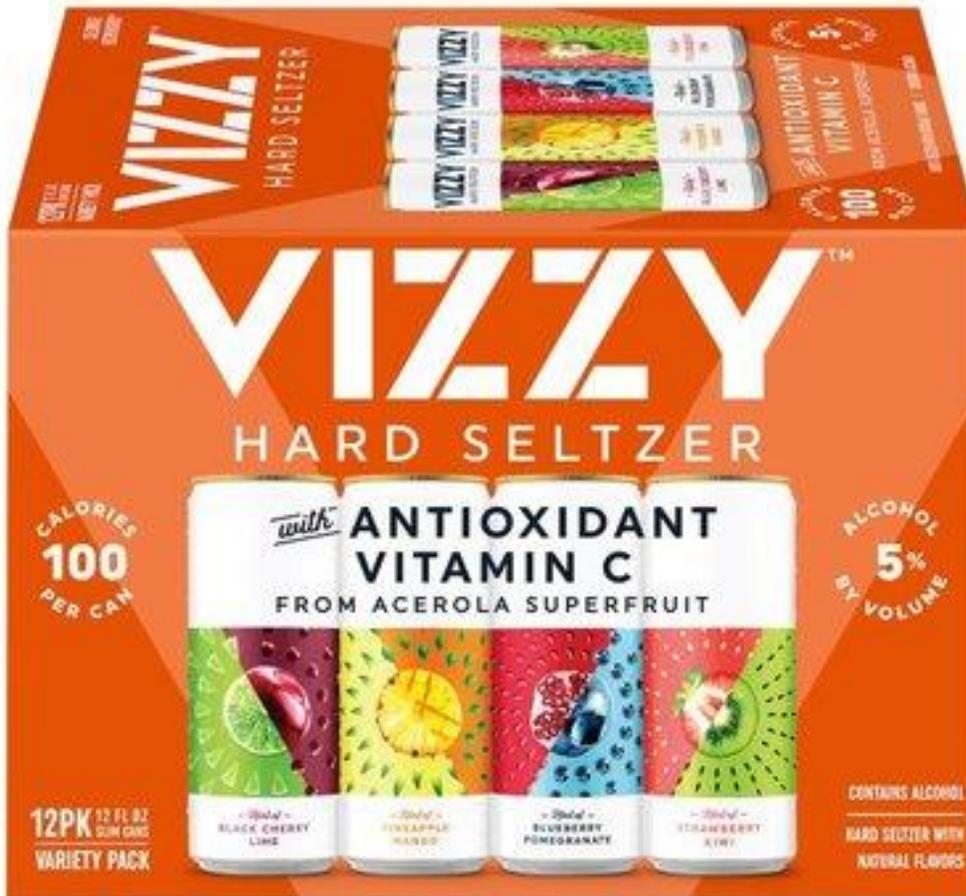
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## Appendix



<https://www.instacart.com/products/21110619-vizzy-variety-pack-beer-12-oz>  
Accessed March 2, 2021

**FIRST HARD SELTZER**  
*Made with*  
**ANTIOXIDANT  
VITAMIN C**  
**FROM ACEROLA SUPERFRUIT**

**CELEBRATE RESPONSIBLY®**  
©2020 MOLSON COORS BEVERAGE CO. MEMPHIS, TN \*BEER

<https://www.instacart.com/products/21110619-vizzy-variety-pack-beer-12-oz>  
Accessed March 2, 2021



**ANOTHER  
HARD SELTZER?**

**YEAH, BUT WE'VE GOT  
ANTIOXIDANT  
VITAMIN C**

**GET VIZZY**

<https://www.vizzyhardseltzer.com/#about-us>

Accessed March 2, 2021

<b>Nutrition Facts</b>	
<b>Serving size 1 can</b>	
<b>Amount per serving</b>	
<b>Calories 100</b>	
<b>% Daily Value</b>	
<b>Total Fat</b> 0g	<b>0%</b>
<b>Sodium</b> 30mg	<b>1%</b>
<b>Total Carbohydrate</b> 2g	<b>1%</b>
Total Sugars 1g	
Includes <1g Added Sugars <b>2%</b>	
<b>Protein</b> 0g	
Iron 0.4mg 2% • Vit C 18mg 20%	
Not a significant source of saturated fat, trans fat, cholesterol, dietary fiber, vitamin D, calcium and potassium.	

**INGREDIENTS:** SPARKLING WATER, CANE SUGAR, NATURAL FLAVOR, PINEAPPLE JUICE CONCENTRATE, CITRIC ACID, SODIUM CITRATE AND DRIED ACEROLA CHERRY JUICE

<https://www.vizyehardseltzer.com/sites/vizyehardseltzer/files/2020-06/Vizy-Pineapple-Mango-SF.jpg>

Accessed March 2, 2021

*- Hint of -*  
**BLACK CHERRY LIME**

**INGREDIENTS:** SPARKLING WATER, CANE SUGAR, NATURAL FLAVORS, CHERRY JUICE CONCENTRATE, CITRIC ACID, SODIUM CITRATE AND DRIED ACEROLA CHERRY JUICE

*- Hint of -*  
**PINEAPPLE MANGO**

**INGREDIENTS:** SPARKLING WATER, CANE SUGAR, NATURAL FLAVOR, PINEAPPLE JUICE CONCENTRATE, CITRIC ACID, SODIUM CITRATE AND DRIED ACEROLA CHERRY JUICE

*- Hint of -*  
**BLUEBERRY POMEGRANATE**

**INGREDIENTS:** SPARKLING WATER, CANE SUGAR, NATURAL FLAVOR, POMEGRANATE JUICE CONCENTRATE, CITRIC ACID, SODIUM CITRATE AND DRIED ACEROLA CHERRY JUICE

*- Hint of -*  
**STRAWBERRY KIWI**

**INGREDIENTS:** SPARKLING WATER, CANE SUGAR, NATURAL FLAVOR, KIWI JUICE CONCENTRATE, CITRIC ACID, SODIUM CITRATE AND DRIED ACEROLA CHERRY JUICE

<https://www.hy-vee.com/grocery/PD53170772/Vizzy-Hard-Seltzer-Variety-Pack-12Pk>

Accessed March 2, 2021

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<sup>1</sup> CSPI is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health through better nutrition and safer food. We do not accept government or corporate grants and are supported primarily by the approximately half million subscribers to our *Nutrition Action Healthletter*. CSPI provides nutrition and food safety information directly to consumers, and has long advocated for legislation, regulation, and judicial rulings to ensure that food labels and advertising are clear and transparent, and that they convey useful and relevant public health information.

<sup>2</sup> The Consumer Federation of America (CFA) is an association of non-profit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy, and education. Today, more than 250 of these groups participate in the federation and govern it through their representatives on the organization's Board of Directors.

<sup>3</sup> While most alcoholic beverage labeling is regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB), the FDA oversees labeling of certain beers that do not meet the definition of a "malt beverage" under the Federal Alcohol Administration Act. Sugar-based hard seltzers meet the definition of FDA-regulated beers. *See* U.S. Food and Drug Administration. Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration: Guidance for Industry. December 2014. <https://www.fda.gov/media/90473/download>. Accessed March 2, 2021.

<sup>4</sup> U.S. Food and Drug Administration. *Questions and Answers on FDA's Fortification Policy: Guidance for Industry*. 2015. <https://www.fda.gov/media/94563/download>.

<sup>5</sup> 21 U.S.C. § 343.

<sup>6</sup> Lieber CS. Relationships Between Nutrition, Alcohol Use, and Liver Disease, Relationships Between Nutrition, Alcohol Use, and Liver Disease. National Institutes of Health. 2004. <https://pubs.niaaa.nih.gov/publications/arh27-3/220-231.htm>

<sup>7</sup> U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans 2020-2025. 2020. p49. [https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary\\_Guidelines\\_for\\_Americans\\_2020-2025.pdf](https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf)

<sup>8</sup> Lieber CS. Alcohol: its metabolism and interaction with nutrients. *Annu Rev Nutr.* 2000;20:395-430.

<sup>9</sup> Lieber CS. Relationships Between Nutrition, Alcohol Use, and Liver Disease, Relationships Between Nutrition, Alcohol Use, and Liver Disease. National Institutes of Health. 2004. <https://pubs.niaaa.nih.gov/publications/arh27-3/220-231.htm>

<sup>10</sup> U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans 2020-2025. 2020. p49. [https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary\\_Guidelines\\_for\\_Americans\\_2020-2025.pdf](https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf)

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> Lieber CS. Alcohol: its metabolism and interaction with nutrients. *Annu Rev Nutr.* 2000;20:395-430.

<sup>14</sup> 21 C.F.R. § 104.20.

<sup>15</sup> 45 Fed. Reg. 6314 (Jan. 25, 1980).

<sup>16</sup> *Id.*

<sup>17</sup> 21 C.F.R. § 104.20.

<sup>18</sup> *Id.*

<sup>19</sup> U.S. Food and Drug Administration. *Questions and Answers on FDA's Fortification Policy*. 2015. <https://www.fda.gov/media/94563/download>

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> 21 U.S.C. § 321(f).

<sup>23</sup> U.S. Food and Drug Administration. Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration: Guidance for Industry. 2014. <https://www.fda.gov/media/90473/download>

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> 21 U.S.C. § 343(a).

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- <sup>28</sup> U.S. Food and Drug Administration. *Questions and Answers on FDA's Fortification Policy*. 2015. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-fdas-fortification-policy>
- <sup>29</sup> 21 C.F.R. § 104.20.
- <sup>30</sup> 45 Fed. Reg. at 6314.
- <sup>31</sup> U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans 2020-2025. 2020. [https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary\\_Guidelines\\_for\\_Americans\\_2020-2025.pdf](https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf)
- <sup>32</sup> *Id.*
- <sup>33</sup> *Id.*
- <sup>34</sup> Lieber CS. Alcohol: its metabolism and interaction with nutrients. *Annu Rev Nutr.* 2000;20:395-430.
- <sup>35</sup> 21 U.S.C. § 343(a).
- <sup>36</sup> Vizzy hard Seltzer. n.d. <https://www.vizzyhardseltzer.com/>.
- <sup>37</sup> 21 C.F.R. § 104.20(h).
- <sup>38</sup> National Library of Medicine. *Ascorbic Acid*. PubChem. <https://pubchem.ncbi.nlm.nih.gov/compound/Ascorbic-acid>. Accessed March 10, 2021.
- <sup>39</sup> 21 C.F.R. § 101.13(b)(2)(ii) (A nutrient content claim is a “claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling.”).
- <sup>40</sup> 21 U.S.C. § 343(r).
- <sup>41</sup> 21 C.F.R. §§ 101.54(b), (c).
- <sup>42</sup> 21 C.F.R. §101.54(c).
- <sup>43</sup> U.S. Food and Drug Administration. Food Labeling Guide: Guidance for Industry. 2013. <https://www.fda.gov/media/81606/download>; U.S. Food and Drug Administration. Warning letter to Dr. Pepper Snapple Group. August 30, 2010. <https://www.fdalabelcompliance.com/letters/ucm224571>.
- <sup>44</sup> *With*. Merriam-Webster. <https://www.merriam-webster.com/dictionary/with#synonyms> (“[U]sed as a function word to indicate . . . presence.”). Accessed March 2, 2021; *Contains*. Merriam-Webster. <https://www.merriam-webster.com/dictionary/contains#synonyms> (“[T]o have within.”) Accessed March 2, 2021.
- <sup>45</sup> 21 U.S.C. § 343(r). FDA regulation impose additional requirements for nutrient content claims, such as Vizzy’s, using the term “antioxidant,” *see* 21 C.F.R. § 101.54(g), but those additional requirements are not relevant here.
- <sup>46</sup> U.S. Food and Drug Administration. *Questions and Answers on FDA's Fortification Policy*. 2015. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-fdas-fortification-policy>. (emphasis added) (citing 21 C.F.R. § 101.4 (h)).
- <sup>47</sup> 45 Fed. Reg. at 6314.
- <sup>48</sup> *Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food*, 58 Fed. Reg. 2302, 2396 (Jan. 6, 1993).
- <sup>49</sup> *Id.*
- <sup>50</sup> 45 Fed. Reg. at 6316 (FDA would consider “amendment of current-food labeling regulations” when “necessary” to protect against misleading claims based on fortification.).