

January 25, 2017

The undersigned submits this petition under the Administrative Procedure 5 U.S.C. 553(e); and the FDA's citizen petition procedure as laid out in 21 C.F.R. 10.25 and 21 C.F.R. 10.30 and section 201(n), 403A, and 701(a) of the Federal Food, Drug, and Cosmetic Act to request that the Commissioner of Food and Drugs amend regulations regarding health and nutrient content claims for packaged foods to include a disqualifying level for added sugar. That is, food companies should not be able to label or advertise foods as healthy or nutritious if the amount of added sugar exceeds an FDA-determined percent of calories per serving.

### **A. Action Requested**

We request that the FDA designate a disqualifying nutrient level for added sugars for health and nutrient content claims on food and beverages in sections 21 CFR 101.13 and 21 CFR 101.14 21 CFR 101.13.

### **B. Statement of Grounds**

The mission of the Food and Drug Administration is to “protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled.”<sup>1</sup> The agency was created to “promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner.”<sup>2</sup> The FDA has the authority and the charge to amend regulations expediently when evidence warrants. We petition the agency to restrict the ability of companies to mislead consumers with nutrient and health claims for certain packaged food products despite excessive added-sugar content.

### **Excessive Added Sugar Consumption and Health Impacts**

As the Dietary Guidelines Advisory Committee (DGAC) found in its exhaustive review of the scientific literature, excessive sugar consumption—whether from sugar cane, sugar beets, corn or other sources—has been implicated in numerous health problems. Among the committee's 2015 findings were:

- There is *strong* evidence that dietary patterns lower in sugar-sweetened foods and beverages and higher in fruits, vegetables, and whole grains are associated with a lower risk of cardiovascular disease;
- There is *moderate* evidence indicating that diets higher in whole grains, moderate in dairy products and low in sugar-sweetened foods and beverages are associated with better health outcomes related to healthy body weight and obesity risk;
- There is *moderate* evidence that dietary patterns high in whole grains, vegetables and fruits and low in refined grains and sugar-sweetened beverages reduce the risk of the onset of type 2 diabetes;
- There is *limited* evidence suggesting that dietary patterns during childhood or adolescence high in refined grains and sugar-sweetened foods and beverages increases the risk of obesity long-term. This determination is a result of a general paucity of literature on children included in the committee's review.<sup>3</sup>

Scientific research continues to generate a body of evidence for a causal relationship between sugar consumption and weight gain and between sugar consumption and the rise in the incidence of the major chronic metabolic diseases (i.e. type 2 diabetes, cardiovascular disease, high triglycerides, and hypertension).<sup>4</sup> This association between sugar and metabolic disease is found separate from sugar's effect on total calorie intake and exclusive of its effect on obesity. For instance, new evidence implicates high sugar consumption with an increased risk for cardiovascular mortality, independent of the link

between sugar and obesity.<sup>5</sup> Fructose, a simple sugar present in both white sugar and high fructose corn syrup, has been shown to contribute to metabolic diseases. Fructose can cause hyperinsulinemia (excessive insulin in the blood stream) and hyperuricemia (excess uric acid),<sup>6</sup> and both of these are predictors of chronic metabolic disease. Fructose also contributes to non-alcoholic fatty liver disease,<sup>7</sup> which is a primary risk factor for development of diabetes.

Studies have shown that sugar consumption can activate parts of the brain associated with reward and craving and that high sugar consumption can trigger addiction-like behaviors.<sup>8</sup> In addition, added sugars, particularly from sugar-sweetened beverages, are a source of harmful calories because they displace calories in other, more nutritious foods and this effect is especially concerning at the level at which they are consumed by many Americans.<sup>9</sup>

In 2015, the Department of Human Health and Services (DHHS) and the US Department of Agriculture (USDA) followed the DGAC's guidance and responded to the scientific evidence by recommending, for the first time in the history of the *Dietary Guidelines for Americans*, that added sugars constitute less than 10 percent of a person's daily caloric intake.<sup>10</sup> This move was in line with recommendations from other major scientific institutions. In 2015, the World Health Organization strongly recommended that adults and children limit added sugars intake to less than 10 percent of their total daily caloric intake and advised that a reduction to five percent or less would be more beneficial.<sup>11</sup> The United Kingdom's Scientific Advisory Committee on Nutrition's working group on carbohydrates intake found that added-sugar consumption in adults and children is associated with risk of dental caries, diabetes, and obesity and recommended reducing intake to 5 percent of daily calories in order to substantially decrease the disease risk.<sup>12</sup>

It sends dangerous mixed messages to consumers for guidance and nutrition standards on the one hand to limit added sugars and yet to continue to allow food companies to make health claims on sugar-rich processed foods. The science behind the relationship between added sugars and chronic disease risk is clear, and the FDA should ensure that its labeling rules account for this risk and are protective of human health.

### **Children's Excessive Sugar Consumption**

While more research is needed to fully understand the health effects of added sugars on infants and young children, the existing literature points to a troubling trend. There is abundant evidence that sugary foods and beverages in children's diets cause dental caries.<sup>13</sup> A diet high in added sugars is also associated with an increased risk of obesity in children.<sup>14</sup> Consumption of sugary beverages, such as sodas and fruit drinks, is associated with overweight and obesity among children between two and five years of age.<sup>15</sup> And, children who consume sugar-sweetened beverages during infancy are twice as likely to be obese as those who did not. Researchers found that the odds of obesity at six years of age did not depend on the age of introduction of sugar-sweetened beverages during infancy or the average weekly intake, just that it happened at all.<sup>16</sup> Evidence shows that exposure to sugar early in life can lead to lifelong expectations and preferences for sweet foods.<sup>17</sup> In other words, the preference for sweet tasting foods stays with children as they grow.<sup>18</sup>

The American Heart Association recently recommended that the two-to-five-year age group avoid consumption of added sugars in food and beverages altogether because "there is minimal room for nutrient-free calories in the habitual diets of very young children." Children aged two to five currently consume an average of 53 grams of sugar per day, which is over two times the DGAC recommended level of ten percent of daily caloric intake.<sup>19</sup> More must be done to address added sugar overconsumption in order to improve the health of all Americans, especially the youngest and most vulnerable, in which taste preferences are just forming. Giving parents and caregivers the tools they need to make informed

decisions about foods they feed their children is crucial to informed, responsible decision-making. And ensuring that claims on food packages do not mislead consumers by trumpeting health benefits of sugar-rich products would be a step in the right direction.

### **Disqualifying Levels for Health Claims Should Include Added Sugars**

Not only is there robust evidence on the link between added sugars and chronic disease, but other agencies and respected public health organizations—even food companies—have acknowledged the scientific justification for reduced added sugar consumption. In the 2015-2020 *Dietary Guidelines*, the DHHS and USDA include the DGAC recommendation of limiting added sugar consumption to less than 10 percent of daily caloric intake for children two and older as well as adults. It is also important to note that the *Dietary Guidelines* places added sugars with sodium, saturated fats, and *trans* fats calories in the same category of calories that should be limited as a part of a healthy eating pattern.<sup>20</sup>

In 2010, the Healthy Hunger-Free Kids Act brought nutrition standards for schools into accord with dietary guidelines, codified by the USDA's 2012 final rule.<sup>21</sup> These standards included limits to the amount of salt, saturated fat and sugar in children's meals at school, subsequently adopted by the Child and Adult Food Care Program and the Supplemental Food Program for Women, Infants and Children (WIC).<sup>22</sup> In light of the most recent *Dietary Guidelines*, the National Academy of Medicine's Food and Nutrition Board released recommendations to the USDA for additional changes to the WIC food package, including ways to further reduce added sugar content for young children.<sup>23</sup>

Further, industry-led voluntary guidelines for advertising advise restricting added sugar along with salt and fat. The Children's Food and Beverage Advertising Initiative's marketing guidelines' "Nutrients to Limit" include salt, fat, *and* sugar.<sup>24</sup>

### **Consumers Misled Into Thinking that Products with Added Sugars are Healthy**

In FDA's definition, misbranded foods have false or misleading labels, are not properly named or identified, are missing required disclosures or nutrition information, or fail to make health and nutrition claims in accordance with specific instructions.<sup>25</sup> Claims on food packages are more abundant now than ever before and often lead consumers to underestimate calorie content and overestimate positive attributes.<sup>26</sup> A study of 115 child and family cereal brands found that many of the least healthy brands marketed to children contained the highest amount of health claims.<sup>27</sup> Because consumers are interested in eating so-called healthy foods, it is not surprising that health claims which lead consumers to believe a food is healthy would drive those sales.<sup>28</sup> However, it is imperative to FDA's mission of protecting public health that these claims are accurate and that they don't lead consumers to believe a product is healthier than it really is.

### **FDA's Authority to Prohibit Misleading Food Claims**

When the FDA first codified the US Nutrition Labeling and Education Act of 1990, it created disqualifying levels for total fat, saturated fat, cholesterol and sodium because public health experts recommended that American consumers limit intake of these nutrients that were "known to increase the risk of disease."<sup>29</sup> Over two decades have passed, and in that time, a body of scientific evidence has demonstrated the link between sugar consumption and chronic heart disease, diabetes, and obesity. Major scientific organizations have recommended that American consumers limit intake of added sugars to reduce their risk of chronic disease, which complies with the FDA's own reasoning behind setting disqualifying levels for fat, saturated fat, cholesterol and sodium in 1993:

“As explained in the proposal to establish DRV’s (55 FR 29476), the values for fat, saturated fat, cholesterol, and sodium were based on recommendations that American consumers limit or reduce dietary intake of these nutrients in order to lower their risk of a number of diet-related diseases whose incidence in the general population is considered by the vast majority of public health experts to be unacceptably high.”<sup>30</sup>

Thus, the FDA should reconsider its thirty-year-old evaluation of disease risk for excessive added-sugar intake, since many public health experts would now argue that the risk of obesity, diabetes, and cardiovascular disease are in fact “unacceptably high.”

Additionally, when the FDA first wrote its rule on disqualifying levels for other nutrients, it explicitly noted that it could not set a level for added sugar without a daily reference value (DRV), which at the time did not exist for added sugar:

“Moreover, the public health community has not identified a dietary level above which consumption of sugars has been demonstrated to increase the risk of a disease. Thus, the agency finds that there is no sound basis on which to establish the requested DRV for sugars. Accordingly, the agency is declining to set a disqualifying level for added sugars at this time.”

However, with the 2016 revisions to the nutrition facts label, the FDA has set DRVs for added sugar at 25 grams for ages one to three and 50 grams for ages four and up.<sup>31</sup> Now that the FDA has DRVs for added sugar, and overwhelming evidence has illustrated that excessive added sugar consumption is linked to several chronic diseases, it is time for the FDA to reconsider adding a disqualifying level for added sugar.

After the FDA includes added sugar to its list of nutrients with disqualification levels, it should ensure that manufacturers making nutrient content claims are not able to deceive consumers to believe a product with excessive added sugar is healthier than it actually is. For example, the FDA has issued draft guidance on redefining the nutrient content claim “healthy;” a disqualifying level of added sugars should be part of those requirements.<sup>32</sup> Since there is overwhelming evidence that excessive added sugar consumption is not part of a healthy eating pattern, the FDA should include added sugar restrictions for nutrient content claims, including those that are implied.

## **Conclusion**

With the accumulating scientific knowledge linking sugar consumption to weight gain and several chronic diseases—type 2 diabetes, cardiovascular disease, high cholesterol, and high blood pressure, the FDA should amend its rules so that food companies can no longer make health or nutrient claims on foods with high sugar amounts. Over 30,413 individuals from all fifty states and Washington, D.C. have signed onto this petition in support of a disqualifying level for added sugar (See Appendix). The FDA must take advantage of this clear opportunity to improve the information on and quality of foods based on the current science, helping Americans to make informed choices in order to live long, healthy lives.

## **C. Environmental Impact**

As a request for “issuance, amendment, or revocation of procedural or administrative regulations and guidance documents,” this petition is categorically exempt from the requirement of either an environmental impact statement or an environmental assessment under 21 C.F.R. 25.30(h).

## **D. Economic Impact**

An assessment of economic impact will be submitted at the request of the Commissioner, per 21 CFR 10.30(b)(3).

## E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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<sup>1</sup> 21 USC 383(b)(2) (2012)

<sup>2</sup> 21 USC 393(b)(1) (2012)

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