



November 1, 2017

Division of Dockets Management  
Food and Drug Administration  
Room 1061, HFA-305  
5630 Fishers Lane  
Rockville, MD 20852

**Re: Docket No. FDA-2012-N-1210**

**Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Proposed Extension of Compliance Dates**

The Society for Public Health Education strongly opposes any delay of the updated Nutrition Facts label regulations and requests that the FDA not delay the compliance dates.

The Society for Public Health Education (SOPHE) is a 501 (c)(3) professional organization founded in 1950 to provide global leadership to the profession of health education and health promotion. SOPHE contributes to the health of all people and the elimination of health disparities through advances in health education theory and research; excellence in professional preparation and practice; and advocacy for public policies conducive to health. SOPHE is the only independent professional organization devoted exclusively to health education and health promotion. Members include behavioral scientists, faculty, practitioners, and students engaged in disease prevention and health promotion in both the public and private sectors. Collectively, SOPHE's 4,000 national and chapter members work in universities, medical/health care settings, businesses, voluntary health agencies, international organizations, and all branches of federal/state/local government.

This revision represents the first comprehensive overhaul of the Nutrition Facts label since its appearance on packaged foods in 1994. The updated Nutrition Facts labels are easier for consumers to understand and use, and also provide critical information that consumers need to make healthy food choices, including a line for added sugars, more prominent disclosure of calorie content, more accurate serving sizes, updated percent Daily Values (DVs), and new, required disclosures of nutrients of public health concern. The proposed delay would mean that the label would go 27 years without a major update for all affected products. Consumers should not have to wait an additional year and a half to have access to this important information.

The public health urgency of keeping to the original compliance dates is underlined by the recent release of national obesity data from the Centers for Disease Control and Prevention (CDC), showing unacceptably high and rising prevalence rates. The CDC reported all-time high prevalence—almost 40 percent of adult Americans have obesity and almost 19 percent of youth have obesity.<sup>1</sup> These new data also underscore the health inequity of the obesity epidemic, with CDC reporting that the “overall prevalence of obesity was higher among non-Hispanic black and Hispanic adults than among non-

Hispanic white and non-Hispanic Asian adults.”<sup>2</sup> SOPHE urges the FDA not to delay the Nutrition Facts label compliance dates and move forward with implementing the regulations with the original timeline. In May, more than 40 scientists and researchers wrote to then-Secretary Price and Commissioner Gottlieb, urging that the compliance date not be delayed.<sup>3</sup> Also, in May, 11 health departments from the Big Cities Health Coalition wrote the Secretary and Commissioner opposing a delay, saying the updated labels were critical to helping them protect the health of their communities.<sup>4</sup> In June, 29 public health organizations made the same request,<sup>5</sup> citing the public health importance of the updated label. SOPHE opposes the proposed delay for the following reasons:

**1) Updating the Nutrition Facts label is already long overdue.**

As noted in the preamble to the 2016 final rule for the Nutrition Facts update, FDA issued three advance notices of proposed rulemaking related to the label between 2003 and 2007.<sup>6</sup> But it was not until 2014 that FDA actually issued a proposed rule to update the Nutrition Facts label. In short, the need for updating the label has been evident for well over a decade. The issuance of the proposed rule, the supplemental provision on added sugars, and publication of the final rule in May 2016 has been quite expeditious, and that sense of urgency should continue to pervade FDA’s approach to compliance, especially given the emerging public health need cited above with the new CDC data, as well as the 2015 Dietary Guidelines for Americans.

**2) An example of public health harm from delaying compliance: Consumers cannot follow the 2015 Dietary Guidelines for Americans’ advice on added sugars or potassium without the updated Nutrition Facts label’s mandatory disclosures.**

The current Nutrition Facts label does not disclose the amount of added sugars in foods, yet that information is crucial to help consumers comply with the Dietary Guidelines for Americans’ recommendation to limit daily added-sugars consumption to less than 10 percent of calories (e.g., 50 grams in a 2,000-calorie diet).<sup>7</sup> Even if consumers could recognize all the forms of added sugar listed in the ingredient label—such as fructose, maltose, sucrose, honey, evaporated cane juice, and concentrated fruit juice—they could not possibly estimate the added sugars in a food.

Declaration of added sugars on the Nutrition Facts label is of great public health importance, especially given that two out of three adults and one out of three children are overweight or obese,<sup>8</sup> one out of three adults now have prediabetes,<sup>9</sup> and as many as one out of three adults could have diabetes by 2050.<sup>10</sup> It is particularly important to differentiate naturally occurring and added sugars—as the updated Nutrition Facts label will do—because people should be consuming *more* of the foods that contain naturally occurring sugars, such as fruit and low-fat dairy products, which are part of a healthy eating pattern.

Until the updated Nutrition Facts label is used consistently across the marketplace, consumers cannot follow advice from federal or other public health authorities to limit consumption of added sugars to lower their risk of weight gain, CVD, type 2 diabetes, the metabolic syndrome, gout, or dental caries.

Current consumption levels of added sugars can lead to serious health problems. Strong evidence shows that consuming sugar-sweetened beverages—the largest source of added sugars in Americans’ diets—leads to weight gain.<sup>11</sup> A systematic review commissioned by the World Health Organization (WHO) concluded that “intake of free sugars or sugar sweetened beverages is a determinant of body weight.”<sup>12</sup> The 2015 Dietary Guidelines Advisory Committee found “strong” evidence that added

sugars from food and/or beverages are associated “with excess body weight in children and adults” and with the “risk of type 2 diabetes among adults.”<sup>13</sup> Furthermore, added sugars are associated with an increased risk of dying of cardiovascular disease (CVD), high blood pressure, high LDL cholesterol, and triglyceride levels,<sup>14,15</sup> and sugar-sweetened beverages are associated with an increased risk of CVD, metabolic syndrome, gout, and dental caries.<sup>16,17,18,19</sup>

Additionally, the mandatory declaration of potassium on Nutrition Facts labels is a critical public health need that will go unmet until the updated label is in the marketplace. The 2010 DGA, the then-Institute of Medicine, and the 2015 Dietary Guidelines Advisory Committee have highlighted the role of potassium in lowering blood pressure by blunting the adverse effects of sodium on blood pressure.<sup>20,21,22</sup> According to NHANES 2003–2006, only about two percent of the general population has potassium intakes above the Adequate Intake of 4,700 mg from foods or from foods plus supplements.<sup>23</sup> However, some people with certain medical conditions, such as diabetes, or those taking medications that can impair potassium excretion, such as ACE inhibitors, angiotensin receptor blockers, and potassium-sparing diuretics, may need to avoid consuming too much potassium because of potential adverse cardiac effects (arrhythmias).<sup>24</sup> Without a declaration of potassium on the Nutrition Facts label, individuals cannot comply with medical advice on potassium.

**3) A delay keeps consumers from benefiting from the updated Nutrition Fact label’s refreshed design, including the larger and bolder type size for key information and clearer labeling of the nutrient content of a single-serving container.**

Prominent labeling of calories and serving sizes is critical for the two-thirds of adults and one third of youth who have overweight or obesity, and for millions of normal-weight Americans who want to avoid weight gain. While calorie information has been included on the Nutrition Facts label since its inception, it has not been sufficiently prominent. Instead, calorie content is shown in the same type size as the levels of cholesterol, sodium, and several other nutrients. Information on calories is particularly important considering the prevalence of obesity and the resulting diseases, disabilities, and costs.

Delaying the updated Nutrition Facts label will also deny consumers timely access to nutrient information based on the container size for items that could reasonably be consumed in one sitting. For those products containing less than 200 percent of the Reference Amount Customarily Consumed (RACC), the updated Nutrition Facts label will disclose calorie and other nutrient content per container.

For instance, some large beverage companies already voluntarily label 20-ounce bottled drinks as one serving, but many soft drinks, sports drinks, microwaveable soup bowls, single-serving bags of chips, and other foods label each container as containing multiple servings. The proposed delay will also postpone implementation of dual-column labeling, which will also present calorie and nutrient disclosures per container for packages that contain 200–300% of the RACC. Critically, this update allows consumers monitoring their sodium intake, for example, to see the sodium content of an entire 19-oz. can of soup.

**4) Many major food companies have already begun using the updated label or have made commitments to meet the original July 2018 compliance date.**

This delay is not needed to assist the food industry—indeed, the delay creates uncertainty, disruption, and competitive hurdles for many. In fact, major food companies welcomed the changes to the updated Nutrition Facts label. Mars, Inc., announced its “full support for the inclusion of an ‘added sugars’

declaration and the daily value for added sugar,” noting its commitment to “[help] progress transparency and consumer understanding of critical nutrition information.” Nestlé United States president of corporate affairs Paul Bakus stated, “Nestlé applauds the FDA for taking these bold steps that will help consumers make more informed choices in the grocery aisle.” Since the announcement of the updated label, several larger companies have publicly committed to meeting the original compliance date of July 2018; these companies include Mars, Inc., Panera Bread, Campbell’s, the Hershey Co., and KIND.<sup>25</sup> According to Label Insight, a firm that tracks food labeling, an estimated 8,000 products already carry the new label.<sup>26</sup> The Center for Science in the Public Interest has also informally tracked the updated Nutrition Facts label and has found that dozens of companies are already using the updated label.<sup>27</sup>

This is consistent with the history of industry compliance the last time such a change was required: The food industry was able to meet FDA’s deadline for implementing the first Nutrition Facts labeling regulations in 1994, although the compliance date was less than 18 months after the final rules were published and those rules were the first ever to require the label.

**5) Delaying the compliance date for the updated Nutrition Facts label creates a confusing and unfair hodgepodge of different labels in the marketplace.**

As described above, many food and beverage companies are already using the updated Nutrition Facts label on their products, and more will do so. However, an inconsistent application of the updated Nutrition Facts label in the marketplace—which will be exacerbated by the proposed delay in the compliance date—makes it difficult to compare products that feature the updated label with products that do not.

For instance, while two products may contain comparable levels of added sugars, the product without the updated label may appear to contain no added sugars when compared to a product with the updated label that includes a line for added sugars. Similarly, the updated label features new Daily Values for total fat, total carbohydrate, dietary fiber, sodium, potassium, calcium, and vitamin D. Therefore, when comparing the DVs between products with the current label and products with the updated label, the percentages are different despite the same absolute amount. This is further complicated by the lack of absolute amounts of vitamins and minerals on the previous label. The updated label also includes updated serving sizes that are more reflective of what people actually eat today. Therefore, products with the updated label feature different serving sizes than products with the current label, making it difficult to compare between products.

**6) FDA should issue guidance expeditiously and can provide enforcement discretion to provide flexibility for compliance while maintaining original timeline.**

A primary reason offered by FDA for the delay is the lack of final guidance that the agency needs to provide industry on issues such as added sugars and dietary fiber. Therefore, the most appropriate course of action is for the agency to commit to a timely and expeditious completion of this guidance. To accommodate industry, the agency can elect to exercise enforcement discretion in those instances where awaiting the guidance prevents companies from a timely compliance with the original deadlines.

In summary, we strongly urge the FDA not to delay to the Nutrition Facts label compliance date and move forward with a timely implementation. The updated Nutrition Facts label will provide

information consumers need to select healthier foods for themselves and their families. Please contact Dr. Cicily Hampton at ([champton@sophe.org](mailto:champton@sophe.org)) or 202-408-9804 with any additional questions.

Sincerely,



Elaine Auld, MPH, MCHES  
Chief Executive Officer

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<sup>1</sup> Hales CM, Carroll MD, Fryar CD, Ogden CL. Prevalence of obesity among adults and youth: United States, 2015–2016. National Center for Health Care Statistics, Centers for Disease Control and Prevention. October 2017. Data Brief No. 288. Available at <https://www.cdc.gov/nchs/products/databriefs/db288.htm>.

<sup>2</sup> Hales CM, Carroll MD, Fryar CD, Ogden CL. Prevalence of obesity among adults and youth: United States, 2015–2016. National Center for Health Care Statistics, Centers for Disease Control and Prevention. October 2017. Data Brief No. 288. Available at <https://www.cdc.gov/nchs/products/databriefs/db288.htm>.

<sup>3</sup> Letter from health scientists and researchers to Secretary Price and Commissioner Gottlieb opposing a delay to the updated Nutrition Facts Label. May 26, 2017. Available at <https://cspinet.org/sites/default/files/attachment/nfl-scientists.pdf>.

<sup>4</sup> Big Cities Health Coalition. Letter to Secretary Price and Commissioner Gottlieb regarding the Nutrition Facts label. May 31, 2017. Available at <https://static1.squarespace.com/static/534b4cdd4b095a3fb0cae21/t/5931975a37c58109d82620f6/1496422235065/Nutrition+Fact+Label+Sign+On+Letter.pdf>.

<sup>5</sup> Letter from health organizations to Secretary Price and Commissioner Gottlieb opposing a delay to the updated Nutrition Facts Label. September 22, 2017. Available at <https://cspinet.org/sites/default/files/attachment/updated-nutrition-facts.pdf>.

<sup>6</sup> 81 FR 103 at 33746.

<sup>7</sup> U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015–2020 Dietary Guidelines for Americans. 8th Edition. December 2015. Available at <https://health.gov/dietaryguidelines/2015/guidelines/chapter-2/a-closer-look-at-current-intakes-and-recommended-shifts/>.

<sup>8</sup> Centers for Disease Control and Prevention. FastStats – Obesity and overweight. May 14, 2014. Available online: <http://www.cdc.gov/nchs/faststats/obesity-overweight.htm>.

<sup>9</sup> Centers for Disease Control and Prevention. National Diabetes Statistics Report. 2017. Available online <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.

<sup>10</sup> Centers for Disease Control and Prevention. At A Glance 2016: Diabetes. Available online <https://www.cdc.gov/chronicdisease/resources/publications/aag/pdf/2016/diabetes-aag.pdf>.

<sup>11</sup> De Ruyter JC, Olthof MR, Seidell JC, et al. A trial of sugar-free or sugar-sweetened beverages and body weight in children. *N Engl J Med*. 2012; 367:1397–406.

<sup>13</sup> U.S. Department of Health and Human Services and U.S. Department of Agriculture. (2015). Scientific Report of the 2015 Dietary Guidelines Advisory Committee. Available at <http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/04-Integration.pdf>.

<sup>14</sup> Te Morenga L, Mallard S, Mann J. Dietary sugars and body weight: systematic review an meta-analyses of randomized controlled trials and cohort studies. January 15, 2013. *BMJ*. 345:e7492.

<sup>15</sup> Yang Q, Zhang Z, Gregg EW, et al. Sugars intake and cardiovascular disease mortality among US adults. *JAMA Intern Med*. 2014; 174:516–24.

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- <sup>16</sup> Malik VS, Popkin BM, Bray GA, et al. Sugar-sweetened beverages, obesity, type 2 diabetes mellitus, and cardiovascular disease risk. *Circulation*. 2010; 33:2477–83.
- <sup>17</sup> Malik VS, Popkin BM, Bray GA, et al. Sugar-sweetened beverages and risk of metabolic syndrome and type 2 diabetes: a meta-analysis. *Diabetes Care*. 2010; 121:1356–64.
- <sup>18</sup> Choi HK, Curhan G. Soft drinks, fructose consumption, and the risk of gout in men: prospective cohort study. *BMJ*. 2008; 336:309–12.
- <sup>19</sup> Tougher-Decker R, van Louveren C. Sugars and dental caries. *Am J Clin Nutr*. 2003; 78:881S-892S.
- <sup>20</sup> U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2010*. 7<sup>th</sup> Edition, Washington, DC: U.S. Government Printing Office, December 2010.
- <sup>21</sup> National Academy of Sciences, Institute of Medicine, Food and Nutrition Board. *Dietary Reference Intakes for water, potassium, sodium, chloride, and sulfate*. Washington, DC: National Academies Press, 2005.
- <sup>22</sup> U.S. Department of Health and Human Services and U.S. Department of Agriculture. (2015). Scientific Report of the 2015 Dietary Guidelines Advisory Committee. Available at <http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/04-Integration.pdf>.
- <sup>23</sup> 79 FR 11880 at 11925.
- <sup>24</sup> National Academy of Sciences, Institute of Medicine, Food and Nutrition Board. *Dietary Reference Intakes for water, potassium, sodium, chloride, and sulfate*. Washington, DC: National Academies Press, 2005.
- <sup>25</sup> Center for Science in the Public Interest. Bringing Consumers the Updated Nutrition Facts Label. July, 2017. Available at <https://cspinet.org/sites/default/files/attachment/companies-menu.pdf>.
- <sup>26</sup> Xavier D. Exponential growth in new label adoption a win for the industry and consumers. *Label Insight*. July 28, 2017. Available at <http://blog.labelinsight.com/exponential-growth-in-new-label-adoption-a-win-for-the-industry-and-consumers>.
- <sup>27</sup> Center for Science in the Public Interest. Updated Nutrition Facts label. *Pinterest*. Available at <https://www.pinterest.com/cspinutrition/updated-nutrition-facts-label/>.