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October 31, 2017

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

Re: Docket Nos. FDA-2012-N-1210 & FDA-2004-N-0258

Dear Sir or Madam:

The American Heart Association (AHA) is extremely disappointed with the Food and Drug Administration's (FDA) proposal to extend the compliance dates for the updated Nutrition Facts label. We oppose the delay and urge the Agency to move forward with the original compliance deadlines.

Delaying the updated Nutrition Facts label would limit consumers' ability to make informed, healthier choices based on current nutrition science. This is extremely concerning given the impact that diet has on cardiovascular and overall health. The rise in obesity rates and the prevalence of heart disease, stroke, diabetes, and cancer underscore the need to provide consumers with up-to-date and easy to understand nutrition information as soon as possible.

An 18-month delay is also unnecessary. Thousands of food and beverage products are already using the new Nutrition Facts label, illustrating that the food industry can meet the original compliance deadlines. In addition, extending the deadlines would result in a longer transition period where consumers see both the old and the new versions of the label in the marketplace. We are concerned that this could lead to increased confusion.

For these reasons, we urge the FDA to maintain the original compliance dates of July 26, 2018 and July 26, 2019, as determined by annual company sales.

Updating the Nutrition Facts Label is Overdue

It has been more than 20 years since the Nutrition Facts label was first introduced, and diet and health information has evolved significantly during that time. The Nutrition Facts label, however, has remained largely unchanged.

The new revisions represent the first comprehensive update to the label since 1994. The revisions are aligned with the Dietary Guidelines for Americans and reflect current nutrition science. For example, the updated Nutrition Facts label will provide consumers – for the first time – with information on the amount of added sugars a product contains. This information is crucial to help consumers comply with the Dietary Guidelines’ recommendation to limit added sugars consumption to less than 10% of calories. Added sugars are generally devoid of any nutrient value and are a significant source of excess calories. Added sugars are associated with a higher body weight and an increased risk of type 2 diabetes, hypertension, tooth decay, obesity, stroke, and coronary heart disease.¹

The new label will also contain a lower Daily Value for sodium of 2,300 mg, based on the current Upper Limit. As with added sugars, lowering sodium consumption is a critical public health goal. Excess sodium consumption is strongly associated with the development and worsening of high blood pressure and an increased risk for stroke, heart failure, kidney failure, gastric cancer, and osteoporosis.^{2,3} More than 85 million – or 34% of all adults in the U.S. – have high blood pressure, and this number is projected to increase to 41.4% of all adults by 2030.⁴ Alarmingly, hypertension is also rising in children and adolescents – 11% of children and adolescents age 8 to 17 have high blood pressure or borderline hypertension, placing them at risk for future health effects.⁵

The new label adds two nutrients of concern – potassium and vitamin D – as mandatory declarations. Potassium helps blunt the adverse effects of sodium on blood pressure; yet fewer than 2% of Americans get the recommended amount.⁶ Low vitamin D intake can affect calcium absorption, the immune system, and overall health, and may be associated with more severe strokes and poor health post-stroke.⁷

¹ Scientific report of the 2015 Dietary Guidelines Advisory Committee. February 2015.

² Appel LJ, et al. The importance of population-wide sodium reduction as a means to prevent cardiovascular disease and stroke: a call to action from the American Heart Association. *Circulation*. 2011;123:1138-1143.

³ Whelton PK, et al. Sodium, blood pressure, and cardiovascular disease: Further evidence supporting the American Heart Association sodium reduction recommendations. *Circulation*. 2012;126:2880-2889.

⁴ American Heart Association. Heart Disease and Stroke Statistics 2017.

⁵ Ibid.

⁶ Cogswell ME, et al. Sodium and potassium intakes among U.S. adults: NHANES 2003-2008. *Am J Clin Nutr* 2012, vol 96, pp. 647-57.

⁷ Low vitamin D predicts more severe strokes, poor health post stroke. American Heart Association News. February 11, 2015. <https://news.heart.org/low-vitamin-d-predicts-severe-strokes-poor-health-post-stroke/>.

Unfortunately, until the updated Nutrition Facts label is used consistently in the marketplace, consumers will not have access to this vital nutrition information. Consumers will find it difficult, if not impossible to follow advice from the Dietary Guidelines, AHA, or other public health authorities.

Consumers will Benefit from the Refreshed Design

The updated Nutrition Facts label uses a refreshed design that more prominently displays the number of calories, the number of servings, and the serving size. In addition, serving sizes have been adjusted to more accurately reflect the typical amount consumed.

While calorie and serving size information have been on the Nutrition Facts label since its inception, it has not been prominently displayed. Instead calorie and serving size content have been shown in the same type size as the levels of fat, cholesterol, and several other nutrients.

More prominent display of this information will be essential for consumers. When the standards for the Nutrition Facts label were first established, 23% of American adults were obese. Unfortunately, obesity rates have risen significantly since that time in all age and gender groups, including children. According to a recent Centers for Disease Control and Prevention report, almost 40% of adults and nearly 19% of youth are now obese.⁸ As noted above, the rise in obesity and subsequent chronic disease underscores the need to call more attention to calorie content and serving size without delay.

Many Products Already Use the New Label

An 18-month delay is not necessary to help the food industry meet the original compliance deadlines. Several major food companies have already publicly committed to meeting the original deadlines, including Campbell's, Hershey Co., KIND, Mars, Inc., and Panera Bread. In addition, an estimated 8,000 products are already using the new label.⁹ This indicates that companies have sufficient time to update their labels by the July 2018 and July 2019 deadlines. (The Agency can also exercise enforcement discretion on a case-by-case basis when a company, despite a good faith effort, can demonstrate that it is unable to comply with the original deadlines.)

Notably, the food industry has shown that it can implement similar requirements in less time. For example, when the Nutrition Facts label was first created, companies had less than 18 months to comply after the final rules were published. It is worth noting that companies met that deadline even though they had to create the new label from scratch. We believe that companies should be able to update an existing label in less time.

⁸ Hales, CM, et al. Prevalence of obesity among adults and youth: United State, 2015-2016. National Center for Health Care Statistics, Centers for Disease Control and Prevention. October 2017. Data Brief No. 288.

⁹ Xavier D. Exponential growth in new label adoption a win for the industry and consumers. Label Insight. July 28, 2017. <http://blog.labelinsight.com/exponential-growth-in-new-label-adoption-a-win-for-the-industry-and-consumers>.

We are, however, aware that some trade associations representing the food industry are asking for *more* time than the 18-month extension the FDA has proposed. Some have suggested that more time is needed to update the labels, including time to redesign and print new packaging. Others have recommended that the compliance date for the updated Nutrition Facts label should be harmonized with upcoming Genetically Modified Organisms (GMO) labeling to minimize the number of times product packaging must be updated. While we understand the rationale behind this request, AHA strongly objects to linking the two label updates, especially since the GMO regulations have not yet been developed and are years away from implementation. In addition, if companies can routinely update their product packaging for promotional purposes, such as using a holiday theme or a movie tie-in,¹⁰ they should be able to update their label to communicate important nutrition information to the public.

Different Labels in the Marketplace May Confuse Consumers

Delaying the compliance deadlines will result in a longer transition period where both the old and new Nutrition Facts labels are on the market. We are concerned that this will confuse consumers.

It will be difficult for consumers to compare and evaluate products when the labeling differs between them. For example, a consumer selects two different varieties of yogurt to compare. One yogurt bears the current Nutrition Facts label, while the other uses the updated label. The two products may contain comparable levels of added sugars, but that may not be readily apparent to the consumer. The yogurt without the updated label may appear to have no added sugars when compared to the product with the updated label that includes the added sugars line. Similarly, the updated label contains a lower Daily Value for sodium. Therefore, a consumer comparing the Daily Value between two different soups – one with the current label and one with the updated label – will see two different percentages even if the absolute amount of sodium is the same.

Because the new label also updates the serving sizes to better reflect the amount typically consumed, consumers will face similar difficulty when comparing products that show two different serving sizes.

We urge the FDA to work toward minimizing this transition period, not make it longer.

Implementing Guidance Should be Issued Immediately

According to the FDA, the proposed delay will give the Agency time to provide the food industry with additional guidance and respond to technical questions. The FDA has already issued draft guidance documents on dietary fiber, added sugars, and food categories used to determine serving size; however, these guidance documents have not been finalized. To help the food industry meet the original compliance deadlines, the FDA should finalize these documents and

¹⁰ See <https://cspinet.org/resource/food-industry%E2%80%99s-frequent-food-label-changes-over-time> for examples.

release them immediately. In addition, to accommodate any lingering industry concerns, the Agency can elect to exercise enforcement discretion in those instances where awaiting the guidance documents prevent companies from timely compliance with the original deadlines.

Evaluating the Costs and Benefits of a Delay

Finally, we are disappointed that the proposed rule and accompanying regulatory impact analysis appear to place company profits over public health. Both documents refer to a reduction in costs to food manufacturers as the “principal benefit” of the Agency’s proposal. This concerns us greatly. The true benefit of providing updated nutrition information is that it will allow consumers to make informed, healthier choices; the Agency’s primary focus should not be on creating “benefits” or cost savings for the food and beverage industry.

We are also concerned that the FDA appears to be justifying the delay by estimating the cost savings to food manufacturers at \$1 billion over 20 years, while estimating the “costs” or “foregone benefits to consumers” at \$0.9 billion over 20 years.¹¹ However, the Agency acknowledges that there are “potential shortcomings related to [the FDA’s] estimates of the Rule’s benefits” to consumers.¹² Because of these shortcomings, the foregone benefits to consumers could actually outweigh the cost savings to manufacturers. It is unclear how the Agency can move forward with a cost-benefit analysis it has acknowledged may be incorrect.

In closing, AHA urges the FDA not to delay the updated Nutrition Facts label. Instead, the Agency should focus on helping food manufacturers meet the original compliance deadlines and make the health of the consumer its first priority.

If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop of AHA staff at (202) 785-7908 or susan.k.bishop@heart.org.

Sincerely,



John J. Warner, MD
President
American Heart Association

¹¹ Food and Drug Administration. Preliminary Regulatory Impact Analysis/Preliminary Regulatory Flexibility Analysis. Food labeling: Revision of the Nutrition and Supplement Facts Label 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 sizes for breath mints; and technical amendments; extension of compliance dates.

¹² Ibid.