



October 30, 2017

Anna K. Abram
Deputy Commissioner for Policy, Planning, Legislation, and Analysis
U.S. Food and Drug Administration
Division of Dockets Management
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20852

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

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

Dear Deputy Commissioner Abram:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the U.S. Food and Drug Administration's (FDA) proposed rule to extend the compliance dates for the updated Nutrition Facts label and serving size regulations. ACS CAN is the nonprofit, nonpartisan advocacy affiliate organization of the American Cancer Society (ACS) dedicated to eliminating cancer as a major health problem. ACS CAN supports legislative, regulatory, and policy efforts that will make cancer a top national priority.

For reasons discussed in more detail below, ACS CAN strongly urges the FDA to retain the existing compliance dates as provided under the May 2016 final rules to update the Nutrition Facts label and serving size requirements. We strongly [support](#) FDA's 2016 final rules¹ and urge that they be implemented without delay. To that end, in February 2017, ACS CAN – along with more than 25 other nutrition and public health organizations – sent a [letter](#) to Health and Human Services Secretary Price asking that the Nutrition Facts label compliance dates not be delayed.

Established Link Between Diet and Cancer

Poor diet, physical inactivity, excess weight, and excess alcohol consumption are major risk factors for cancer, second only to tobacco use. In fact, one in five of the estimated 1.7 million cancer cases expected to be diagnosed this year can be attributed to these factors.² Excess weight is clearly associated with an increased risk of developing 13 cancers, including cancers of the female breast (postmenopausal), colon and rectum, uterus, kidney, pancreas, ovary, liver, gastric cardia, gall bladder,

¹ ACS CAN provided comments to FDA on the agency's [proposed rules to update the Nutrition Facts label](#) and [serving size requirements](#) and on the [supplemental proposed rule to update the Nutrition Facts label](#). We are pleased with the 2016 final rules to update the Nutrition Facts label and serving size requirements.

² American Cancer Society. *Cancer Facts & Figures 2017*. Atlanta, GA: American Cancer Society, 2017.

and thyroid, and adenocarcinoma of the esophagus, meningioma, and multiple myeloma.³ Recent data shows that obesity rates remain high and continue to increase among both youth and adults.⁴ Currently 18.5 percent of youth and 39.8 percent of adults are obese,⁵ increasing their risk for cancer and many other costly chronic diseases.

As a result of the clear relationship that diet and body weight have with many types of cancer, ACS's guidelines for cancer prevention⁶ and cancer survivorship⁷ recommend eating a healthy diet, with an emphasis on plant foods. Specific dietary recommendations include choosing foods and beverages in amounts that help achieve and maintain a healthy weight, limiting processed meats and red meats, and consuming fruits, vegetables, and whole grains instead of refined grain products and other high-sugar foods.⁸ Recent research has found that non-smoking adults who followed ACS guidelines for weight control, diet, physical activity, and alcohol consumption lived longer and had a lower risk of dying from cancer and cardiovascular disease than those who did not.^{9, 10}

Reasons for Opposing the Extension of the Compliance Dates

ACS CAN opposes the proposed delay of the compliance dates for several key reasons:

Consumers need access to up-to-date and useful information to aid them in making healthy food and beverage choices. The update to the Nutrition Facts label represents the first comprehensive revision of the label since it was first required to be on packaged foods in 1994. As FDA stated in the preamble to the February 2014 proposed rule to update the Nutrition Facts label, the label update was needed due to the high rates of diet-related chronic diseases, updated nutrition research and consensus reports, and the need to make the label more useful for consumers. The updated label is based on current research and the formatting and content updates help to address today's diet-related health problems, including the high rates of childhood and adult obesity. The updated Nutrition Facts label is formatted so that it is easier for consumers to understand and use and provides critical information that consumers need to make healthy food choices, including disclosure of added sugars, more prominent disclosure of calorie content, more accurate serving sizes, updated percent Daily Values (DVs), and updated disclosure of nutrients of public health concern, like calcium and Vitamin D. Delaying implementation of the updated label restricts people's access to this information and makes it harder for them to make healthier food choices.

Consumers cannot follow the recommendation to limit their consumption of added sugars without the updated label. An important component of the updated Nutrition Facts label is the addition for the first time of information about added sugar content - as a subset of total sugars - and a DV for added

³ Lauby-Secretan B, Scoccianti C, Loomis D, et al. Body Fatness and Cancer – Viewpoint of the IARC Working Group. *N Engl J Med* 2016; 375: 8.

⁴ Hales CM, Carroll MD, Fryar CD, and Ogden CL. Prevalence of Obesity Among Adults and Youth: United States, 2015-2016. NCHS Data Brief No. 288. October 2017. Available at <https://www.cdc.gov/nchs/products/databriefs/db288.htm>. Accessed October 24, 2017.

⁵ Ibid.

⁶ Kushi LH, Doyle C, McCullough M, et al. American Cancer Society Guidelines on Nutrition and Physical Activity for Cancer Prevention. *CA Cancer J Clin* 2012; 62:30-67.

⁷ Rock CL, Doyle C, Demark-Wahnefried W, et al. Nutrition and Physical Activity Guidelines for Cancer Survivors. *CA Cancer J Clin* 2012; doi: 10.3322/caac.21142.

⁸ Kushi, 2012.

⁹ Kohler LN, Garcia DO, and Harris RB. Adherence to Diet and Physical Activity Cancer Prevention Guidelines and Cancer Outcomes: A Systematic Review. *Cancer Epidemiol Biomarkers Prev* 2016; 25(7): 1018-28.

¹⁰ McCullough ML, Patel AV, Kushi LH, et al. Following Cancer Prevention Guidelines Reduces Risk of Cancer, Cardiovascular Disease, and All-Cause Mortality. *Cancer Epidemiol Biomarkers Prev* 2011; 20(6): 1089-97.

sugars to put the amount in context. Based on evidence of the link between consumption of added sugars and excess body weight, the *Dietary Guidelines for Americans, 2015-2020*, recommends that Americans limit consumption of added sugars to no more than 10 percent of calories.¹¹ Added sugars provide excess calories without any nutrients. The Dietary Guidelines recommendation and the evidence on which it is based is a key reason that the updated Nutrition Facts label includes a line for added sugars. Currently, for foods that may contain both naturally-occurring and added sugars, such as yogurts, juices, flavored milks, dried fruits, and some cereals, trail mixes, and granola bars, it is impossible for consumers to determine how much added sugar the product contains.

The delay also prevents consumers from benefiting from the larger and bolder type size for key information, such as calories, in the updated Nutrition Facts label and clearer labeling of the nutrient content of a single-serving container. Calorie information is the most important information for helping people manage their weight. Prominent labeling of calories and serving sizes is critical for all Americans who want to lose weight or avoid weight gain, since two thirds of adults and one third of youth who are overweight or obese.^{12, 13} The updated Nutrition Facts label makes calorie, serving size, and servings per container information larger and more prominent. This information assists people in making healthier choices necessary for weight management.

Another important component of the May 2016 final rules is a requirement for the Nutrition Facts label to provide nutrient information for the entire package for items that could reasonably be consumed in one sitting and for dual-column labeling for products that may be consumed in one sitting by a single person or across multiple sittings or by multiple people. Delaying implementation of the updated Nutrition Facts label will also deny consumers timely access to this information. Research cited in the February 2014 proposed rule to update the Nutrition Facts label shows that consumers do not accurately calculate the total calories and other nutrients they will consume when eating a portion that is different from the labeled serving size. The updated serving sizes and dual column labeling are essential to empower people to effectively use the Nutrition Facts label to understand the calorie and nutrient content of the foods and beverages they are consuming.

The proposed rule does not appropriately consider the public health benefits of maintaining the existing compliance dates. The proposed rule cites FDA's decision to delay implementation of the label in order to balance the importance of ensuring the industry has sufficient time to comply with the new requirements and decreasing industry costs against the importance of minimizing the transition period during which consumers will see both the old and new versions of the label in the marketplace. We agree that minimizing consumer confusion is important, and another reason why the compliance date should not be delayed. However, FDA should also consider the importance of consumers having access to up-to-date nutrition labels that will help them make healthy choices that will reduce their risk of costly and debilitating diet-related chronic diseases like cancer.

¹¹ U.S. Department of Health and Human Services and U.S. Department of Agriculture. Chapter 2: Shifts Needed to Align With Healthy Eating Patterns. *Dietary Guidelines for Americans, 2015-2020*. 2016. Available at <https://health.gov/dietaryguidelines/2015/guidelines/chapter-2/a-closer-look-at-current-intakes-and-recommended-shifts/>. Accessed October 26, 2017.

¹² Fryar CD, Carroll MD, Ogden CL, et al.. Prevalence of Overweight and Obesity Among Children and Adolescents: United States, 1963-1965 Through 2011-2012.. Centers for Disease Control and Prevention (CDC). September 2014. Available at http://www.cdc.gov/nchs/data/hestat/obesity_child_11_12/obesity_child_11_12.pdf. Accessed July 14, 2016.

¹³ CDC. Obesity and Overweight. April 2016. Available at <http://www.cdc.gov/nchs/fastats/obesity-overweight.htm>. Accessed October 27, 2017.

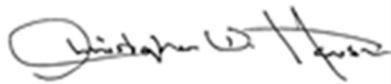
FDA should issue guidance expeditiously and can provide enforcement discretion on the compliance deadline, as needed, while maintaining the original timeline. The proposed rule states that a primary reason for delaying the compliance dates is the lack of final guidance for industry on technical issues such as added sugars and dietary fiber. Therefore, FDA should commit to completing this guidance expeditiously. The final rule to update the Nutrition Facts label was released more than a year ago, thus allowing the agency sufficient time to provide the needed guidance. To accommodate any outstanding industry concerns, FDA could exercise enforcement discretion in the instances where awaiting the guidance prevents companies from meeting the original compliance dates.

Conclusion

In summary, we urge FDA to retain the existing compliance dates for the updates to the Nutrition Facts label and serving size requirements. Delaying the compliance dates keeps consumers from making informed decisions that can improve their health and reduce their cancer risk.

Thank you for considering our comments. If we can provide any additional information or if you have any questions, please contact Melissa Maitin-Shepard, MPP, Senior Analyst, Policy Analysis and Legislative Support, at Melissa.maitin-shepard@cancer.org or 202-585-3205.

Sincerely,

A handwritten signature in black ink, appearing to read "Christopher W. Hansen". The signature is stylized and written in cursive.

Christopher W. Hansen
President
American Cancer Society Cancer Action Network