August 1, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Food Labeling: 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 Rule (Docket No. FDA-2004-N-0258; RIN 0910-AF23)

To Whom It May Concern:

The American Cancer Society Cancer Action Network strongly supports the Food and Drug Administration’s (FDA) proposal to make changes to serving sizes, Reference Amounts Customarily Consumed (RACCs), and dual column labeling on the Nutrition Facts label. The American Cancer Society Cancer Action Network (ACS CAN) is the nonprofit, nonpartisan advocacy affiliate organization of the American Cancer Society (the Society) 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.

Poor nutrition, physical inactivity, and excess weight are major risk factors for several common types of cancer, second only to tobacco use. One fourth to one third of all cancer cases\(^1\) and up to one third\(^2\) of the estimated 585,720 cancer deaths expected to occur in the US this year\(^3\) can be attributed to these three factors. Overweight and obesity are clearly associated with an increased risk of developing cancers of the breast in postmenopausal women, colon and rectum, endometrium, kidney, esophagus, pancreas, and probably gallbladder.\(^4\) Overweight and obesity may also be associated with an increased risk of cancer of the liver, non-Hodgkin lymphoma, multiple myeloma, cancer of the cervix, cancer of the ovary, and aggressive prostate cancer.\(^5\) As a result of this clear relationship diet and weight status have with many types of cancer, ACS CAN supports multi-faceted, population-based policy approaches to improving nutrition and physical activity. This includes removing barriers to healthy lifestyles, changing social norms, and increasing education and awareness of healthy choices. Providing consumers with access to accurate, science-based information about the nutritional content of food and beverage products will facilitate their making healthier diet and lifestyle choices.

\(^3\) American Cancer Society, 2014.
\(^4\) Kushi et al, 2012.
\(^5\) Ibid.
Our comments on this proposed rule follow. We have also submitted comments on the proposed rule to update the Nutrition Facts label.

**General Support for the Proposed Rule**

We applaud FDA for updating the serving sizes and RACCs for some foods and beverages and for setting requirements for dual column labeling for certain single serving containers. We appreciate that FDA is making these changes in light of new data showing that the amount consumed per sitting for certain types of foods and beverages has changed as well as new consumer research on the use and understanding of the Nutrition Facts label. We believe that, together with the updates to the Nutrition Facts label, these changes will enable consumers to better use the Nutrition Facts label to support their making healthier food and beverage choices. Revisions to the Nutrition Facts label, RACCs, and serving sizes are gravely needed, as there has not been a major update to the label, including changes to the serving size requirements, RACCs, and format and content of the label, since the regulations establishing these requirements were initially promulgated following the passage of the Nutrition Labeling and Education Act of 1990 (PL 101-535). We are pleased that FDA has proposed to make long-needed updates to the Nutrition Facts label and related requirements.

**Single-Serving Containers and Dual Column Labeling**

ACS CAN supports the FDA’s proposal to require packages with less than 200 percent of the RACC to be labeled as a single-serving container and to require dual column labeling for products that contain at least 200 percent and up to 400 percent of the applicable RACC. We agree that products with less than 200 percent of the RACC are likely to be consumed in a single eating occasion and it makes sense to consistently label them as a single serving. We also agree that packages with between 200 and 400 percent of the RACC would sometimes be consumed in a single eating occasion and sometimes shared with others or eaten across multiple occasions, depending on the food, packaging, and consumer, so it makes sense to require dual column labeling for these products. For example, some “King Size” bags of chips, large candy bars, and 20 ounce sodas are marketed to be consumed in a single eating occasion. Other products, such as pints of ice cream, some frozen pizzas, and macaroni and cheese mixes, for example, are sometimes consumed by a single person in one eating occasion and sometimes eaten over multiple meals or by multiple people. Dual column labeling will help consumers understand how many calories and nutrients they will consume if they eat or drink a single serving or the entire container of food. With regard to the format for dual column labeling, we believe the FDA should require manufacturers to list and emphasize the calorie content, at minimum, as calories are one of the most important factors consumers should consider when deciding whether they will eat more than the serving size listed. FDA may also want to consider requiring manufacturers to list all of the nutrient content per serving and per container, which would allow consumers to base decisions on the food product’s overall nutrient profile. FDA should base its decision regarding dual column labeling format on consumer research on what information would be most useful to consumers in deciding the amount of a food or beverage to consume.
Changes to the RACCs

We support the FDA’s proposal to revise the RACCs for certain foods and beverages to reflect the way Americans eat today. Labels that list the nutrition information for serving sizes that no longer reflect current portion sizes are difficult to use and may even be deceptive to consumers. We commend FDA for acting on its existing authority and recognizing the need to revise the RACCs for specific foods.

As FDA notes, the original RACCs were established using U.S. Department of Agriculture (USDA) survey data from 1977-1978 and 1987-1988. Consumption patterns have changed over the past few decades. For example, on average, American adults aged 20 and older consumed 240 more calories per day in 2009–2010, when compared to levels in 1971–1975, mostly due to increased portion sizes of foods and beverages.

Using consumption data from the most recent National Health and Nutrition Examination Surveys (NHANES), 2003-2008, FDA proposes to modify an existing RACC if the median consumption increased or decreased by at least 25 percent, compared to the RACC established in 1993. The FDA states that it also took into account other factors when deciding to modify an existing RACC, including information from citizen petitions, industry comments, and market trends. We agree that these criteria generally make sense but urge the agency to consider some refinements. For example, the change in consumption for some food categories, including canned soup, powdered coffee creamers, aerosol cooking sprays, and pasta with sauce, exceeds 25 percent, but a new RACC was not proposed. These food categories in particular may appear to be relatively low in calories and/or sodium and/or saturated fat when examined in the context of their current RACC, but the nutrient profile declines significantly when the actual amount commonly consumed is taken into consideration. In addition, establishing the cutoff for setting new RACCs at changes of 25 percent or greater neglects some categories that deserve re-evaluation due to their impact on public health – such as pasta and pasta sauces high in calories and saturated fat, like alfredo - as the 25 percent cutoff is somewhat arbitrary. Under the law, FDA is required to define the reference amounts for foods based on the amount of food customarily consumed. We urge FDA to consider whether some additional foods with a smaller percentage change in consumption warrant new RACCs.

Consumer Education Needs

We strongly recommend that FDA take steps to actively address concerns about the possible unintended consequence that some consumers view the serving size on the Nutrition Facts label as a portion size recommendation. We recognize that the RACCs used to calculate serving sizes are required to be based on the amount of food people customarily consume, and are not recommended amounts of

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8 See 79 FR 11990, at 12008.
9 Juan W. Memorandum to file: Consumption estimates for foods for infants and children 1 through 3 years of age and for the general food supply for individuals ages 4 years and older in the United States by general category and product category using data from the National Health and Nutrition Examination Survey, 2003–2008 (NHANES 2003–2008) compared to the 1993 RACCs, and Proposed Changes to RACCs. Feb. 11, 2014.
10 See Pub. L. 101.9(b)(1); 58 F.R. 44039 et seq.
food to eat. However, given the likelihood of confusion among some consumers, we strongly recommend that the FDA include clarifying language on the label by either: 1) denoting the serving size provided as a “typical” serving size or 2) including a footnote to clarify that the serving size is based upon the amount typically consumed, and is not a recommended portion size. Information about the difference between labeled serving size and portion recommendations and the meaning of the change in serving sizes should also be included in other consumer education materials and as part of a larger campaign to educate consumers about the Nutrition Facts label and how they can use it to make more informed food and beverage purchase and consumption decisions. FDA should also consider testing strategies for communicating the meaning of labeled serving size as part of consumer research being conducted by the agency.

Implementation Timeline

The FDA has proposed that the updates to the RACCs, serving size requirements, and Nutrition Facts label take effect 60 days following publication of the final rule, with a two year period for compliance. While we appreciate that it will take food manufacturers time to reanalyze the nutrient content for their products and re-print labels, the industry has ample time to begin preparing based on the changes in this proposed rule. We urge the FDA not to increase the period for compliance or grant across-the-board extensions. The FDA has not made a major change to the Nutrition Facts label in two decades; consumers have waited long enough. To support industry in meeting the proposed timeframe for compliance, FDA should provide implementation guidance and technical assistance following the release of the final regulations to companies needing support.

Additional Labeling Needs

As described in more detail in our comments on the Nutrition Facts label proposed rule, while the proposed updates to the Nutrition Facts label and RACC and serving size requirements represent significant public health advancements and should help consumers make healthier dietary choices, the Nutrition Facts label is only one place consumers look for information about the nutrient content of foods and beverages they are considering purchasing or consuming. As part of a larger strategy to provide consumers with information to support their making more informed food and beverage choices wherever they buy food, FDA should also consider developing a consistent, science-based, easy-to-understand front-of-package labeling system and promulgate final regulations for menu labeling and vending machine labeling. FDA may also want to consider updating the requirements for label claims following the publication of final regulations for the Nutrition Facts label and the RACC and serving size requirements to make these sets of regulations consistent. Taken together, these new requirements for, and improvements to, consumer labeling will support consumers in making more informed and healthier food and beverage choices. These new regulations should also incentivize the food and beverage industry to make changes to improve the nutritional content of the food supply, which will improve long-term diet-related chronic disease risk and overall health.
Conclusion

In conclusion, we believe that the proposed updates to the RACCs, serving size requirements, and Nutrition Facts label will do much to support consumers in making healthier food and beverage choices. We hope that FDA will consider many of our recommendations for strengthening the proposal and look forward to working with the agency in support of a strong final rule.

Thank you again for the opportunity to provide comment on these proposed regulations. If we can provide any additional information or if you have any questions, please contact Melissa Maitin-Shepard, MPP, Senior Analyst, Policy Analysis & Legislative Support, at melissa.maitin-shepard@cancer.org or 202-585-3205.

Sincerely,

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American Cancer Society Cancer Action Network