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

SUMMITTED VIA: www.regulations.gov

Docket No. FDA–2012–N–1210, RIN 0910- AF22

Re: Comments on the proposed rule for Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Extension of Comment Period

On behalf of the American Public Health Association, a diverse community of public health professionals who champion the health of all people and all communities, I thank you for the opportunity to provide comments on Food Labeling: Revision of the Nutrition and Supplement Facts Labels. APHA appreciates the tremendous efforts of the Food and Drug Administration to propose such comprehensive changes to the Nutrition Facts panel. APHA urges the agency to complete consumer research testing all of the changes to ensure they do not have unexpected consequences due to misunderstanding new or revised information. The nutrition label serves as an important tool in educating individuals on how to select the most nutritionally rich foods and a healthy diet. Excessive emphasis on any one nutrient can divert attention from total calories or result in an increase of another nutrient. The information on the label should be justified by science that demonstrates impact on public health.

With the extensive redesign of the Nutrition Facts label, APHA encourages FDA to develop a similar outreach campaign, as ‘Read the Label’, to enable Americans understanding of the revisions and use of the revised nutrition label successfully. To minimize confusion, FDA should try to finalize all the anticipated changes to the food package labels simultaneously, including the Nutrition Facts Panel, a front-of-package panel and health claims. Consumer education about the revisions to the nutrition label should be able to explain all changes at one time, both minimizing consumer confusion and maximizing FDA resources available for education.

To be most effective, FDA should incorporate ‘lessons learned’ on how individuals from various subpopulations interpret the new label design. A successful strategy may be to partner with national public health and nutrition organizations, and state health departments to extend the reach of FDA’s educational resources to all rural and urban communities. Such education needs
to accommodate individuals at various levels of educational achievement and with cultural and ethnic diversity.

APHA will focus its remarks on the following questions for which FDA sought answers:

1. **CALORIES: Calories from fat; Percent DV declaration for calories; Two thousand calories as the reference caloric intake level**

APHA agrees that FDA should no longer include the statement on “Calories from fat” on the Nutrition Facts label in an effort to place greater emphasis on total calories; not include a Daily Reference Value for calories; and retain a calorie intake level for the purpose of nutrition labeling. When attention is placed on a single macro nutrient such as fat, consumers shift attention to other macro nutrients often without lowering total calories. Neither the Food and Nutrition Board or any other scientific body has recommended a specific level of calorie intake for adults; therefore, FDA would not have a basis for determining an appropriate DRV for calories. Total calorie consumption depends on total calorie expenditure; thus, it does not appear justified to establish a DRV for calories. FDA should retain a reference level of calories as it has in the current Nutrition Facts panel as a basis for setting DRVs for macronutrients. A caloric level of 2,000 calories or less should also appear near the calorie content statement to assist consumers in knowing what portion of their total calories the specific food contributes.

2. **SUGARS: Added sugars**

APHA is concerned that continued emphasis on one food component such as added sugars may distract consumers from the more important issues of total calories, large portion sizes and sugar sweetened beverages with high calorie content but no nutrients. As was seen in the past, when one nutrient like total fat becomes the focus on dietary fat, food manufacturers produce low fat foods that are not necessarily lower in calories. Likewise, the emphasis on trans fat has led many food manufacturers and restaurants to simply substitute an oil or solid fat that is high in saturated fat in place of a partially hydrogenated oil instead of replacing the oil high in trans fat with an oil low in saturated fat and trans fat. Similarly, it is possible to replace added sugars with another component and not reduce total calories. Little consumer testing has been conducted to demonstrate consumer knowledge of the meaning of added sugars or to show changed food choices related to added sugars. Further, as FDA notes, there is lack of scientific consensus and evidence connecting added sugars to chronic diseases. To date, nutrition label information has been grounded in science to support public health. APHA urges FDA to maintain the credibility of the Nutrition Facts panel and cautions FDA from requiring the mandatory declaration of added sugars without sufficient evidence.

3. **SODIUM: DRV**

APHA believes it is important for FDA to continue to recommend reductions in dietary sodium content of the U.S. food supply. Although a recent review presents the methodological problems that influence the consistency of research findings about the role of sodium in some health outcomes, there is sufficient evidence for recommending overall reductions in dietary sodium intake at the population and individual levels, at least as it applies to blood pressure as one
marker for cardiovascular disease risk. Despite recommendations to reduce dietary sodium,1,2,3,4,5,6 intake remains high, due in large part to the wide consumption of processed foods and foods eaten away from home which account for most of the sodium in American diets.7,8 APHA supports FDA using a uniform upper level of sodium consumption, while urging the food and restaurant industries to gradually reduce the sodium in their products as the most cost-effective way to reduce sodium in the food supply and lower dietary sodium consumption in the population.9 At the same time it is important to continue to provide ways for consumers to easily identify sodium in their foods through information on food labels and menu notices so they can avoid high sodium foods. In addition, with the relatively rapid emergence of new research in this area it is crucial to regularly monitor for changes and recommendations that can affect policy and program management.

4. ESSENTIAL VITAMINS AND MINERALS THAT ARE MANDATORY: Vitamin A and vitamin C

APHA supports the FDA proposal to no longer require the mandatory declaration of vitamin A and C on the Nutrition Facts panel. The 2010 Dietary Guidelines for Americans no longer identifies vitamin A and C as nutrients of significant public health concern and incidence of inadequate intakes are low. However, these two nutrients are still included in the criteria for one or more of the six essential nutrients required to leverage the FDA definition for 'healthy' and for the minimum criteria for leveraging some health claims. Therefore, FDA needs to address these health claim requirements at the same time. As such, we would still encourage manufacturers to voluntarily label vitamin A and C on the Nutrition Facts panel.

5. ESSENTIAL VITAMINS AND MINERALS THAT ARE VOLUNTARY: Vitamin D and potassium

APHA supports the FDA proposal to require the mandatory declaration of vitamin D and potassium on the Nutrition Fact panel based on their public health significance. The addition of

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vitamin D is important because of its role in calcium absorption, promotion of adequate bone mineralization and reduction of the risk of osteoporosis. Potassium has a positive association with reduced blood pressure, and boosting the ratio of potassium to sodium is proven to mitigate adverse effects of high sodium intake.\textsuperscript{10}

5. FAT: Polyunsaturated and monounsaturated fats

APHA supports the continued voluntary declaration of mono- and polyunsaturated fats, as the 2010 Dietary Guidelines Committee noted a reduced risk of cardiovascular disease when these fats replace saturated fat in the diet.

6. FORMAT: Increasing the prominence of calories and serving size

APHA supports the revised current format that emphasizes calories and serving sizes. The total recommended calories should be shown in a prominent location on the label, as consumers appear to understand and make better selection with calorie content when placed in context.\textsuperscript{11} With all of these revisions, it is important for FDA to actually test the proposed Nutrition Facts panel with consumers to ensure that the proposed font size of the “total number of servings” per package is not mistakenly connected to the calorie amount for the total package. Part of a consumer test could be to make the font size of the “amount per x size serving” and the “calorie amount” equal. Consumers may remain confused by what nutrients, such as saturated fat and cholesterol, should be reduced in the diet and what nutrients, such as dietary fiber should be increased; however, it does not appear that an alternative format that makes this information clearer has been extensively consumer tested and would require extensive consumer education.

Beyond the proposed FDA changes to the Nutrition Facts panel, APHA recommends making improvements to the ingredient list for improved readability and understanding. Currently, the ingredient list is often displayed in small font size, uses complex names and confusing formats. Additionally, related ingredients can be listed separately, which results in ingredients appearing lower on the list. APHA recommends that instead, product manufacturers should be required to aggregate related ingredients. For example, different sweeteners can presently be listed individually. APHA’s proposal would require all forms of sugar to be listed as a single ingredient, which may result in sugar moving to the top of a product’s ingredient list.

**Conclusion**

APHA supports the FDA’s initiative to revise the Nutrition Facts panel and urges the agency to ensure that all final decisions are based on extensive review of the scientific research on nutrition and consumer testing of their understanding of the revised label format and information. Although the subject of front-of-package labeling is outside the scope of this proposed rule, we encourage FDA to finalize the changes to FOP at the same time as the revised Nutrition Facts panel.

\textsuperscript{10} Haddy FJ, Vanhoutte PM, Feletou M. Role of potassium in regulating blood flow and blood pressure. American J Physiol Regul Integr Comp Physiol. 2006; 290(3):R546-52.

\textsuperscript{11} Sinclair S, Cooper M, and Mansfield E. The Influence of Menu Labeling on Calories Selected or Consumed: A Systematic Review and Meta-Analysis. J Academy of Nutrition and Dietetics. Published online July 17, 2014.
panel so that consumers can learn about both changes simultaneously. Thank you for your time, attention and dedication to this essential public health issue.

Sincerely,

Georges C. Benjamin, MD
Executive Director