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June 20, 2005

**VIA EMAIL**

Attention: Docket No. 2004N-0463  
Food and Drug Administration  
Division of Dockets Management (HFA-305)  
5630 Fishers Lane, Room #1061  
Rockville, MD 20852

**Re: The American Heart Association's Comments on the Food and Drug Administration's Request for Public Comments Regarding Advanced Notice of Proposed Rulemaking for Docket No. 2004N-0463.**

To Whom It May Concern:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we submit the following comments in response to both the Food and Drug Administration's (FDA's) advanced notice of proposed rule making (ANPRM) for Food Labeling: Prominence of Calories (Docket No. 2004N-0463).<sup>1</sup>

Since 1924, the American Heart Association has dedicated itself to reducing disability and death from cardiovascular disease and stroke — the #1 and #3 leading causes of death in the United States — through research, education, community based programs and advocacy. AHA's efforts include the development of evidence-based clinical practice guidelines designed to help advise physicians and other providers on the prevention, treatment and chronic management of cardiovascular disease and stroke.<sup>2</sup>

Promoting healthy eating plans and an active lifestyle for Americans is a top priority of AHA. In this regard, we have established a series of dietary

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<sup>1</sup> 70 Fed. Reg. at 17008 (April 4, 2005).

<sup>2</sup> To see a complete listing of AHA guidelines, including joint ACC/AHA guidelines go to: <http://www.americanheart.org/presenter.jhtml?identifier=3004546>

guidelines for both children and adults<sup>3</sup> and have been active in promulgating guidelines for physical activity<sup>4</sup> for use by physicians, clinicians, and the public.

In addition to establishing evidence-based guidelines to promote the health of Americans, the American Heart Association has also been actively engaged in raising public awareness. Most recently, AHA announced its partnership with the Clinton Foundation.<sup>5</sup> The joint goal of the Clinton Foundation–American Heart Association alliance is to stop the increasing prevalence of childhood obesity in the United States by 2010, fostering an environment where kids pursue a healthy lifestyle into their adulthood.

The AHA firmly believes that better food habits can significantly reduce high blood cholesterol-- one of the major risk factors for cardiovascular disease. Weight loss and weight management are essential to improve cardiovascular health in Americans, given that approximately 65% of the population is overweight or obese. Therefore, AHA takes this opportunity to applaud FDA for publishing this ANPRM, and submits the following comments to be considered by the FDA. For purposes of clarity, we have reiterated the question posed by the FDA as well as our corresponding response.

#### **A. Questions Concerning Prominence of Calorie Information on Food Labels.**

*FDA: Would consumer awareness of the caloric content of packaged foods be increased by amending nutrition-labeling regulations to give more prominence to the declaration of calories per serving? Why or why not?*

AHA: Amending the nutrition labeling regulations to give additional prominence to the declaration of calories per serving size would increase consumer awareness of the caloric content per serving contained in packaged foods.

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<sup>3</sup> Ronald M. Krauss, Robert H. Eckel, Barbara Howard, Lawrence J. Appel, Stephen R. Daniels, Richard J. Deckelbaum, John W. Erdman, Jr, Penny Kris-Etherton, Ira J. Goldberg, Theodore A. Kotchen, Alice H. Lichtenstein, William E. Mitch, Rebecca Mullis, Killian Robinson, Judith Wylie-Rosett, Sachiko St. Jeor, John Suttie, Diane L. Tribble, and Terry L. Bazzarre; AHA Dietary Guidelines : Revision 2000: A Statement for Healthcare Professionals From the Nutrition Committee of the American Heart Association ; Circulation 0: 2296r-2311r

<http://www.americanheart.org/presenter.jhtml?identifier=1330>

<sup>4</sup> Fletcher GF, Balady G, Blair SN, Blumenthal J, Caspersen C, Chaitman B, et al. Statement on exercise. Benefits and recommendations for physical activity programs for all Americans. A statement for health professionals by the Committee on Exercise and Cardiac Rehabilitation of the Council on Clinical Cardiology, American Heart Association. *Circulation*. 1996;94:857-862.

<sup>5</sup> <http://www.americanheart.org/presenter.jhtml?identifier=3030479>

***FDA:** How would a more prominent listing of calorie information change the way consumers use the NFP in deciding what to eat?*

AHA: Although we believe that additional prominence to caloric information would raise consumer awareness, additional research is necessary to determine whether a more prominent listing of calorie information affects how consumers use the nutrition fact panel when making decisions on what food to consume.

***FDA:** What methods could be considered for increasing prominence? For example, should the font size be increased for the listing of "Calories" from the current requirement of 8-point type, and/or should extra bold type or a different style of type be used?*

AHA: The FDA should increase the font size of the calorie listing to a 12-point type on medium to large packages. For smaller packages (such as a can of tuna), we would urge that the font size be no smaller than 10-point type.<sup>6</sup>

Additionally, the use of boldface type would effectively serve to create a greater contrast of the caloric information from the other printed information, and could help draw consumer attention to caloric information included on the nutrition fact panel.

In the past, both the FDA and other government agencies have conducted consumer surveys to determine whether larger type and boldface type would aid consumer awareness. Consumers surveyed regarding over the counter drugs stated to the FDA that both the use of boldface type and larger fonts were instrumental in helping them make informed decisions.<sup>7</sup> Therefore, there is ample precedence for the FDA to make this change to increase prominence and maximize readability.

***FDA:** Would providing for a % DV disclosure for total calories assist consumers in understanding the caloric content of the packaged food in the context of a 2,000 calorie diet? Why or why not?*

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<sup>6</sup> Currently, 10-point type is the smallest font size recommended for written materials circulated to the public:

See 65 Fed. Reg. 81082, 81096 (2000)(citing Kripalani, S., "The Write Stuff: Simple Guidelines Can Help You Write and Design Effective Patient Education Materials," *Texas Medicine*, vol. 91, pp. 40-45, 1995; Backlinger, C.L., and P.A. Kingsley, *Write it Right: Recommendations for Developing User Instructions for Medical Devices Used in Home Health Care*, Department of Health and Human Services, Publication No. FDA 93-4258, 1993; Mettger, W., and J. Mara, *Clear & Simple: Developing Effective Print Materials for Low-Literate Readers*, Bethesda, MD, National Cancer Institute, Publication No. NIH 95-3594, 1994).

<sup>7</sup> [http://www.fda.gov/fdac/features/1997/497\\_otc.html](http://www.fda.gov/fdac/features/1997/497_otc.html)

AHA: Providing for a percentage of daily value for total calories will not facilitate consumer awareness of the caloric content of packaged food, in context of a 2,000-calorie diet. Moreover, the use of % DV of calories on the NFP may have the inadvertent effect of encouraging consumers to infer that 2,000 calories is appropriate for all Americans, when in fact the consumer may require a higher or lower number based on his or her individual lifestyle. For example, a sedentary adult may require less than 2,000 calories a day. In this example, including a % DV may cause a sedentary adult to infer that he or she can consume 2,000 calories, thereby promoting weight gain in such an individual. Therefore, we would urge FDA to conduct a consumer survey on how the public interprets DV information for calories before requiring the inclusion on the nutrition fact panel.

B. Questions Concerning “Calories From Fat”

**FDA:** *How does the listing “Calories from fat” adjacent to “Calories” affect consumers’ focus on the total calories of a food?*

AHA: Anecdotal evidence suggests that displaying “Calories from Fat” adjacent to “Calories” can cause consumer confusion. In some instances, consumer attention may inadvertently be focused solely on the calories from fat, instead of focusing on the total number of calories consumed on one eating occasion.

**FDA:** *What are the advantages or disadvantages of eliminating the listing for “Calories from fat” from the nutrition label?*

AHA: FDA should remove the “calories from fat” language from the nutrition fact panel. Excessive caloric intake will promote weight gain, irrespective of whether the individual consumer derives calories from fat or not. By eliminating “calories from fat” language from the nutrition label, the consumer’s attention will focus on the total calories consumed per serving and total fat (including saturated and trans fats).

**FDA:** *What data would be needed to determine whether the listing of “Calories from fat” is or is not necessary to assist consumers in maintaining healthy dietary practices?*

AHA: If deemed necessary, the AHA would support FDA doing additional research to verify consumer understanding and use of the “Calories from Fat” information.

C. Questions About Use of Calorie Information on Food Labels

**FDA:** *Is calorie content used to determine how much of a given food to eat, or to determine which foods, out of a range of similar products, to eat? Why or why not?*

AHA: Anecdotal evidence, as well as limited consumer focus research, does exist that shows consumers do utilize the caloric information included on the NFP. However, one deterrent to using caloric information is consumers must do math to figure out how many calories are consumed, based on the number of servings eaten. Therefore, FDA should include both the number of calories for the entire food package as well as the number of calories per serving on the NFP .

*FDA: If calorie labeling affects decisions on whether to eat a food and on how much to eat, how would the effects of the following requirements differ: A requirement to display the number of calories per serving on the PDP or a requirement to increase the prominence of the calories per serving in the NFP?*

AHA: Caloric information should only be displayed in conjunction with the portion size and the nutrient information. By disassociating caloric information from nutrient content information, consumers may judge two food products based on calories alone, instead of considering calories in conjunction with the nutrient values, such as vitamins and minerals associated with similar products.

For example, if there are two cereals Brand A and Brand B, both with predominant labels on the front that include calories per serving such as: Brand A has 100 calories per serving and Brand B has 150 calories per serving. The consumer may choose Brand A solely on the basis that it has less calories, when in fact Brand B may have a higher fiber, Vitamin D, Vitamin B-12 and Calcium. Therefore, this may lead to the development of unhealthy eating patterns rather than consumption of an overall healthy and balanced diet.

*FDA: What do consumers currently think the calories on packaged foods represent?*

AHA: We believe that consumers do have problems drawing a link between calories consumed and “serving size.” Therefore, we would support FDA conducting consumer research on this question, and based on the outcome of this research conducting the necessary consumer education.

#### D. Questions About Reformulation of Foods Or Redesign of Packaging

*FDA: If the calorie content per serving were required to be more prominently displayed on the NFP, would it encourage more competition based on the calorie content of the food? Would the result be products reformulated to have fewer calories per serving, for example greater use of no calorie sweeteners? Would it result in any repackaging of products offered? How would this option change the kinds of products offered?*

AHA: Increased competition will depend on the market forces and what the target consumers desire from the food products. Therefore, this may result in the repackaging of certain products geared towards a specific consumer demographic.

**FDA:** *If the calorie content per package were required to be prominently displayed on the PDP, would it encourage more competition based on the calorie content of the food? Would the result be repackaging of products into smaller units, for example repackaging cookies into 100 calorie packages? Would there be any incentive to reformulate under this option? How would this option change the kinds of products offered?*

AHA: Repackaging for products into smaller units may prove to be a useful mechanism to influence the amount of calories consumer by a consumer during an eating occasion, even where calories are not prominently displayed on the PDP.

### **Additional Recommendations and Conclusions:**

The AHA would reiterate that the FDA should require the total calories for the entire package, as well as the calories per serving size on the NFP. Today consumers are forced to calculate the nutrition information by multiplying the number of servings. For example, a bottle of juice may indicate 130 calories, but consumers may have to multiply 130 by the number of servings (which may be 1.5 or 2 or more servings per container). Therefore, we would recommend that the total calories for the container or package be include, as well as the calories per serving.

Additionally, FDA should break out the sugars contained in packaged food into naturally occurring sugars and added sugars. This information would help consumers distinguish from naturally occurring sugars, which may be associated with other vitamins and minerals versus added sugars that are devoid of additional nutrient value. We believe that the people should choose and prepare foods and beverages with little added sugars or caloric sweeteners. Like the USDA, we believe that because sugars contribute calories with few, if any, nutrients consumers should look for those foods and beverages low in added sugars, and notes that Chapter 7 of the USDA dietary guidelines states:

“[T]he 2,000-calorie pattern includes only about 267 discretionary calories. At 29 percent of calories from total fat (including 18 g of solid fat), if no alcohol is consumed, then only 8 teaspoons (32 g) of added sugars can be afforded. This is less than the amount in a typical 12-ounce calorically sweetened soft drink. If fat is decreased to 22 percent of calories, then 18 teaspoons (72 g) of added sugars is allowed. If fat is increased to 35 percent of calories, then no allowance remains for added sugars, even if alcohol is not consumed.<sup>8</sup>”

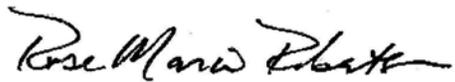
Therefore, to make healthy food choices, it is important for the consumer to be provided with information that allows them to distinguish between added and naturally occurring sugars.

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<sup>8</sup> <http://www.health.gov/dietaryguidelines/dga2005/document/html/chapter7.htm>

For the foregoing reasons, the American Heart Association would strongly encourage to the FDA to modify the existing food labeling requirements related to prominence of calories, so that consumers can make health choices. If you need any additional information, please do not hesitate to contact Penelope Solis, J.D., Manager of Regulatory Relations at (202) 785-7905 or via email at [penelope.solis@heart.org](mailto:penelope.solis@heart.org). We look forward to continue working with you to address the obesity epidemic by creating NFPs that are able to facilitate the ability of consumers to make health choices.

Sincerely,

A handwritten signature in black ink that reads "Rose Marie Robertson". The signature is written in a cursive style with a long horizontal stroke at the end.

Rose Marie Robertson, MD, FAHA  
Chief Science Officer  
American Heart Association