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*Learn and Live*<sup>SM</sup>

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June 17, 2005

**VIA EMAIL**

Attention: Docket No. 2004-0456  
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. 2004-0456.**

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 the Food and Drug Administration's (FDA's) advanced notice of proposed rule making (ANPRM) for Food Labeling: Serving Size of Products that can be Reasonably Consumed in One Eating Occasion (Docket No. 2004-0456).<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>

<sup>1</sup> 70 Fed. Reg. at 17010 (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>

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

***FDA:** Do consumers recognize the differences between serving sizes on food labels and servings recommended in dietary guidelines? What information on a label would help make the distinction clearer?*

AHA: Consumers currently do not recognize the difference between serving sizes on food labels and serving recommended. Therefore, we would recommend tying servings more directly to the dietary guidelines by utilizing per cup, per ounce, per bar, per slice as measurements.

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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: Should FDA initiate rule making to require packages that can reasonably be consumed at one eating occasion to provide the nutrition information for the entire package? If so what criteria should FDA use to determine which multi-serving products would require nutrition information for an entire package? Should it be based on the total amount in the container, the type of food or something else?*

AHA: If the goal of the rulemaking is to promote weight loss and more realistically communicate the caloric content of packaged foods, disclosure of multiple servings would provide the consumer with information, which could assist him or her in regulating weight and making appropriate choices on what to consume. Therefore, AHA strongly recommends that FDA incorporate a dual column on the NFP with one column representing the nutritional information for a single serving size and the other representing the nutrient information in the whole package.

*FDA: Would consumers think that an increase in serving size on food labels means more of the food should be eaten? What additional education efforts should be provided to consumers to avoid such a conclusion?*

AHA: Consumer research would need to be conducted to see if the public is able to distinguish between an increased “serving size” with the “recommended portion” that should be consumed on one eating.

*FDA: We previously stated in the preamble to the serving size final rule under part 101 (21 CFR part 101) (58 FR 2229 at 2235): “Section 403(q)(1)(A)(i) of the act, which states that a serving size is the amount customarily consumed, effectively requires the use of food consumption data as the primary basis for determining serving sizes.” However, considering the issues raised previously in this document, should the agency reconsider its definition of “serving” and “serving size” or how the agency interprets “customarily consumed”?*

AHA: We believe that the FDA should align with Dietary Guidelines definition of “serving sizes” which would facilitate the ability of consumers to get a more accurate assessment of what they are eating from the label. This would help to align all of the nutrition guidance that is currently being disseminated by from various governmental agencies including the Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA). Moreover, it is important that 100 kcal of milk should not be compared with 100 kcal of iceberg lettuce.

### **III. Additional Recommendations and Conclusions:**

In the ANPRM, the FDA asked for a number of questions regarding the use of comparative claims. The American Heart Association does not support the loosening or expanding of standards related to comparative claims.

In addition to the comments included above, we would encourage FDA to include potential warnings for packages that may appear to the consumer to represent one serving size. For example, a 20-ounce soda is usually consumed on one eating occasion and should include a warning such as “This container represents 2.5 servings.”

Moreover, we would reiterate that the FDA should incorporate a dual column on the NFP with one column representing the nutritional information for a single serving, and the other column representing the whole package. The greatest deterrent to use of the nutrition fact panels is that consumers need to do the math. By including this second column, the calculations are provided to the consumer, and may increase the likelihood that they will use this information in making food choices. Modifying the food panel will require consumer re-education on how to read the new NFP.

The AHA would also strongly support additional scientific research to be conducted in the area of portion size. Data exists that food with high energy density are of particular concern, given the raise in obesity. Many laboratory based studies have found that large portions of energy dense foods can lead excess energy intake. However, most studies note that additional research is needed to explore strategies that can be used to moderate the effects of portion size on the food consumed by Americans.<sup>6</sup>

Therefore, the American Heart Association would strongly encourage the FDA to adopt the recommendations delineated in our comments above. 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).

Sincerely,



Chief Science Officer  
American Heart Association

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<sup>6</sup> Ledikwe JH, Ello-Martin JA, Rolls BJ., Portion sizes and the obesity epidemic. Department of Nutritional Sciences, The Pennsylvania State University, University Park, PA, USA. PMID: 15795457