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January 5, 2007

Division of Dockets Management  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Docket No. 2002P-0122

Dear Sir/Madam:

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 appreciate the opportunity to submit our comments in response to the Food and Drug Administration's (FDA) public hearing and request for comments on the regulation of functional foods.

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 and ASA are committed to achieving a reduction in cardiovascular disease, stroke, and associated risk by 25 percent by 2010.

One important strategy for reducing the incidence and risk of cardiovascular disease and stroke is raising the public's awareness of the benefits of a healthy diet and active lifestyle. Promoting healthy eating plans, a healthy body weight, and increased physical activity is a top priority of AHA. The Association firmly believes that better food habits can significantly reduce high blood cholesterol – one of the major risk factors for cardiovascular disease, as well as support appropriate weight management, which is essential to cardiovascular health.

As the public learns more about the relationships between diet and disease, many consumers are trying to adopt a healthier lifestyle and make better food choices. As part of this effort, consumers are purchasing an increasing number of foods that claim

to possess health benefits beyond basic nutrition, or so-called functional foods.<sup>1</sup>

AHA supports the FDA's efforts to examine the regulatory system for functional foods. As the number of functional foods continues to grow and consumers incorporate more of these food products into their diet, it is appropriate for the Agency to explore not only how these products are regulated, but also how they are labeled and marketed to the public. In the *Federal Register* announcement of the public hearing, the FDA posed a number of questions related to these areas. Feedback on these issues could provide the Agency with the information necessary to evaluate the current regulatory process and determine what adjustments, if any, are needed. Unfortunately, AHA is unable to provide responses to many of the questions, because sufficient data on the health benefits of functional foods or on the effect health claims have on consumer purchasing habits does not currently exist.

### ***The Need for Sound, Scientific Evidence***

AHA supports the significant scientific agreement (SSA) standard for health claims. Health claims that meet the SSA standard are based on strong, sound evidence that indicates a relationship between the substance and the health benefit addressed in the health claim. However, other types of claims are not held to the same strict SSA standard. AHA believes that all health claims should be based on sound scientific evidence, and we would support requiring, at a minimum, that the overall strength of the scientific evidence in support of a proposed claim be equal to the evidence that must be submitted for consideration of a SSA claim if a manufacturer chooses to make a qualified or structure/function claim.

To make use of functional food products, consumers need accurate, science-based information about the health consequences of these products. However, the science to support or counter many claims about health benefits is not yet strong enough. A number of dietary constituents have unproven or uncertain health effects. For example, there may be a number of research studies that initially suggest a connection between a nutrient or food and a health effect, but further research studies either do not confirm those results or contradict them. Or there may be a lack of data on the effectiveness of nutrients that are artificially added to foods as compared with the effect of those same nutrients when they naturally occur in foods.

The lack of SSA for many health benefit claims demonstrates the need for additional research in this area. AHA would support efforts to increase the amount of research related to health claims, nutrient content claims, and other labeling claims. And all considered research should be published in peer-reviewed, science journals.

Without better scientific evidence for these claims, consumers must operate under a "buyer beware" mentality. Consumers are bombarded with health messaging. It is confusing, if not impossible, for consumers to determine which claims have merit. Providing the public with scientifically accurate information will provide consumers with the tools to make better decisions about the foods they eat.

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<sup>1</sup> General Accounting Office Report to Congress. Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods". July 2000: pg. 3.

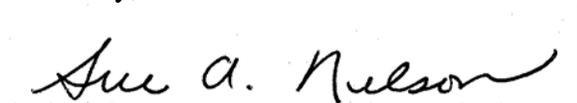
***Consumer Education and Assessment***

AHA recommends that the FDA consider expanding its consumer education campaigns to help consumers better understand nutrition labeling and health messaging on product packages. The Agency should examine the language and symbols used to communicate health claims and determine the best communication strategies to help consumers make healthier food and beverage choices. The Agency's recent experimental study on the effects that qualified health claims for omega-3 fatty acids and monounsaturated fatty acids from olive oil have on consumer perceptions and behavior is a good example. However, the Agency should expand the survey to include other types of health benefit claims, and should make the survey results available to the public. The Agency should also examine ways to communicate the differences between qualified and unqualified health claims, nutrient content claims, and structure/function claims and the strength of the scientific evidence behind each.

In summary, AHA supports the FDA's commitment to examine the regulation of functional foods. As consumers increasingly turn to food products for their health benefits, not just their taste, aroma, or nutritive value, functional foods are gaining significant prominence in the American diet. In order to help consumers make appropriate food choices, the Agency should expand its education efforts to help consumers better understand health benefit claims, as well as publish the results of studies to examine the effects of health claims on the public's behavior. The Agency should also consider the impact that health claims have on changing consumer behavior to make healthier food and beverages choices. We also urge the Agency to examine the need for sound, scientific evidence for all claims about health benefits.

If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop, MA, Regulatory Relations Manager, at 202-785-7908 or via email at [susan.k.bishop@heart.org](mailto:susan.k.bishop@heart.org).

Sincerely,

A handwritten signature in cursive script that reads "Sue A. Nelson". The signature is written in black ink on a white background. To the right of the signature, there is a vertical red line.

Sue Nelson  
Vice President of Federal Advocacy  
American Heart Association