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**Advocacy Department**

Office of Legislative and Regulatory Affairs

1150 Connecticut Ave., NW Ste 300

Washington, DC 20036

Tel 202.785.7900

americanheart.org

May 31, 2005

**VIA EMAIL**

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

**Re: The American Heart Association's Response to the Food and Drug Administration's Request for Comment on Experimental Study of Qualified Health Claims, Consumer Inferences About Omega-3 Fatty Acids and Monosaturated Fatty Acids from Olive-Oil (Docket No: 2005N-0097).**

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) request for public comment on the agency's experimental study of consumer inferences about qualified health claims for omega-3 fatty acids and monosaturated fatty acids from olive oil.<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.

On March 30, 2005, the FDA published a Federal Register (FR) notice announcing a proposed study which would assist the FDA in collecting data concerning qualified health claims (QHCs) and their impact on consumer perceptions and behaviors. The proposed study will focus on two issued qualified health claims to evaluate whether consumers comprehend the information contained within the claim, and whether consumers understand the relative significance of the information contained in the claim within the context of the individual's total diet. Additionally, the study is expected to broaden the agency's understanding of how qualified health claims are interpreted in terms of scientific evidence conveyed by the message and to differences that may exist between the QHCs on dietary supplements versus foods.

<sup>1</sup> 70 Fed. Reg. at 16291 (March 30, 2005).

The two qualified health claims that FDA will study are related to the reduction of risk of coronary heart disease from consumption of monounsaturated fatty acids from olive oil and omega-3 fatty acids, and the language of the two health claims is as follows:

1. Limited and not conclusive scientific evidence suggests that eating about 2 tablespoons (23 grams) of olive oil daily may reduce the risk of coronary heart disease, due to the monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increase the total number of calories consumed in a day. One serving of this product [Name of food] contains [x] grams of olive oil.
2. Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [name of food] provides [x] grams of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat and cholesterol content.]

The American Heart Association supports the agency's efforts to conduct a study that will test consumer understanding of the information represented in these two qualified health claims, so long as the consumer survey is well constructed. Our recommendation is limited to one area that the American Heart Association believes could help maximize the quality, utility and accuracy of the data included in the consumer survey.

We recommend that at a minimum the FDA test the qualified claim language exactly as stated in the Federal Register Notice. The language included in the notice parallels previously approved and released language from last fall in two letters issued by the agency. Should the FDA decide to test modified versions of these two qualified health claims, the AHA would recommend that the Agency test the Federal Register language first with the respondents, so that this can serve as a baseline, before any variations on the QHCs language are tested. We believe that this will maximize the utility of the information rendered by the survey. We also raise the same recommendations with regards to the portion of this study that will explore the difference in message that may exist between dietary supplements and food.

The American Heart Association is committed to working with the FDA to create health claims that are credible, clear and informative, and that allow the public to make informed 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).

Sincerely,



Katherine Krause  
Executive Vice President of Advocacy  
American Heart Association