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February 19, 2008

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

Re: Docket No. 2007N-0464

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) notice on the Reevaluation of Health Claims and Qualified Health Claims.

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. As part of this effort, the Association produces evidence-based clinical guidelines and scientific statements designed to raise awareness of and advise physicians and other providers regarding the prevention, treatment and management of cardiovascular diseases and stroke. Since 1999 when AHA and ASA committed to achieving a 25% reduction in cardiovascular disease, stroke, and associated risk by 2010, the Association's efforts have contributed to a 25.8% reduction in deaths from coronary heart disease – an early achievement of our goal – and a 24.4% reduction from stroke. However, we continue to work toward needed reductions in the major risk factors for these leading causes of death, as well as eliminating disparities in care for women and minority populations.

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 patterns, a healthy body weight, and increased physical activity is a top priority of AHA. The Association

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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 proper weight management, which is essential to cardiovascular health.

As the public learns more about the relationships between diet and disease, many consumers are striving to adopt a healthier lifestyle and make better food choices. Sixty-six percent of consumers report having made dietary changes to improve health, a nine percent increase from the previous year. Additionally, an increasing number of consumers cite healthfulness as an influential factor in food purchasing decisions.[1] AHA supports the dissemination of clear, scientifically valid information to the public to help consumers evaluate and select more nutritious foods. Health claims may serve as a way to achieve this aim.

Soy Protein and Coronary Heart Disease

AHA strongly believes that health claims should be based on strong, sound evidence that indicates an unambiguous relationship between the substance and the health benefit indicated in the health claim. As the science supporting health claims is often evolutionary, AHA applauds the FDA's initiative to reevaluate the soy protein and coronary heart disease (CHD) health claim as new data has become available. In 2000, just one year after the FDA first approved the health claim, an AHA Nutrition Committee Scientific Advisory concluded that "it is prudent to recommend including soy protein foods in a diet low in saturated fat and cholesterol."[2] However, given the volume of well-controlled studies on soy protein and soy-derived isoflavones that have been released since that time, the AHA Nutrition Committee recently undertook a reevaluation of the evidence on soy protein and cardiovascular disease (CVD) to update its scientific advisory. AHA reviewed the literature and considered the effects of soy protein and isoflavones on several other CVD risk factors: HDL cholesterol, triglycerides, lipoproteins, and blood pressure. In 2006, the Association published an updated Scientific Statement titled "Soy Protein, Isoflavones, and Cardiovascular Health."[3] We reaffirmed our position in the Association's "Diet and Lifestyle Recommendations Revision 2006."[4]

In both statements, AHA acknowledges that earlier research indicated that soy protein, as compared with other proteins, potentially had clinically important favorable effects on LDL cholesterol and other CVD risk factors. However, this research has not been confirmed by many studies reported during the past 10 years. The majority of research suggests that a very large amount of soy protein, more than half the daily protein intake, may lower LDL cholesterol by a few percentage points <u>when it replaces dairy protein or a mixture of animal proteins</u>. However,

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[1] International Food and Information Council Foundation 2007 Food and Health Survey: Consumer Attitudes toward Food, Nutrition and Health.

[2] Erdman JW Jr. AHA Science Advisory: Soy protein and cardiovascular disease: a statement for healthcare professionals from the Nutrition Committee of the AHA. *Circulation.* 2000; 102:2555-2559.

[3] Sacks FM, Lichtenstein A, Van Horn L, Harris W, Kris-Etherton P, Winston M; American Heart Association Nutrition Committee. Soy protein, isoflavones, and cardiovascular health: an American Heart Association Science Advisory for professionals from the Nutrition Committee. *Circulation.* 2006; 113:1034-1044.

[4] Lichtenstein A, Appel LJ, et al; American Heart Association Nutrition Committee. Diet and Lifestyle Recommendations Revision 2006: A Scientific Statement From the American Heart Association Nutrition Committee. *Circulation.* 2006; 114; 82-96.

this reduction is very small relative to the large amount of soy protein tested in these studies and the data are mainly from hypercholesterolemic individuals. Furthermore, there are no evident benefits of soy protein consumption on HDL cholesterol, triglycerides, lipoprotein(a), or blood pressure. Thus, the direct cardiovascular health benefit of soy protein or isoflavone supplements is minimal at best.

AHA recognizes that there is research claiming to identify a cholesterol-lowering mechanism of soy protein,[5] and there may be cardiovascular health benefits in using soy proteins to replace foods high in animal protein that contain saturated fat and cholesterol.[6] However, at this time the totality of evidence linking soy protein consumption with reduced risk of coronary heart disease is not sufficient to meet the standards of significant scientific agreement (SSA). Thus, AHA strongly recommends that FDA revoke the soy protein and CHD health claim.

We understand that if the FDA decides to revoke this SSA health claim, the Agency could consider allowing its use as a qualified health claim. We urge FDA not to do so. Consumer research conducted by AHA, FDA, and others has repeatedly shown that despite the presence of qualifying language, consumers do not understand qualified health claims and do not understand that they are based on limited and varying degrees of evidence. Therefore, AHA does not support the use of qualified health claims; only health claims meeting the SSA standard should be permitted.

In conclusion, AHA reiterates our appreciation of the Agency's decision to reevaluate the soy protein and CHD health claim. While the science originally appeared to support a strong link between soy protein and a reduced risk for CHD, recent data are less conclusive and no longer support a SSA level health claim. AHA strongly recommends that FDA revoke the soy protein and CHD health claim. In the meantime, this remains a dynamic area for research. AHA will continue to monitor the science regarding soy and CVD.

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

Sincerely,

Daniel W. Jones, MD
President, AHA

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[5] Cho SJ, Juillerat MA, Lee CH. Cholesterol-Lowering Mechanism of Soybean Protein Hydrolysate. *Journal of Agricultural and Food Chemistry.* 2007; 55; 10599-10604.

[6] Sacks FM, Lichtenstein A, Van Horn L, Harris W, Kris-Etherton P, Winston M; American Heart Association Nutrition Committee. Soy protein, isoflavones, and cardiovascular health: an American Heart Association science advisory for professionals from the Nutrition Committee. *Circulation.* 2006; 113:1034-1044.