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January 10, 2005

Dockets Management Branch (HFA-305)

Food and Drug Administration

5630 Fishers Lane, Room 1061

Rockville, Maryland 20852

Re: Docket No.: 2004N-0458 CFSAN 200477

Dear Dockets Manager:

The Nutrition Committee of the American Heart Association (AHA) is pleased to respond to the following Notices of Availability (NOAs): (a) Regulatory Strategy for the Further Implementation and Enforcement of the Dietary Supplement Health and Education Act of 1994 and (b) Draft Guidelines for Industry.

I'm writing today on behalf of the American Heart Association and its 22.5 million volunteers and supporters. As the largest voluntary health organization, the American Heart Association's mission is to reduce cardiovascular disease and stroke by 25% by 2010. Our organization is unique. Our volunteers include patients, physicians, nurses and other stakeholders dedicated to fighting cardiovascular disease and stroke, our nation's number one and number three killers respectively.

In regard to the NOA (a) as noted above, in general we feel that the guidelines the Food and Drug Administration (FDA) recommends implementing in order to substantiate claims are very good. The examples provided in each section underscore the proper application of the issues FDA chose to highlight. The explanations of different types of studies, observational versus intervention (clinical trials) are accurate and appropriately address the biases inherent in both. The level of detail provided in this section and that on design factors affecting a study is excellent and should be very informative to the reader. They provide a good summary of criterion to determine causality with direct application to the study of dietary supplements. The NOA (a) does note that the "gold standard is a randomized,(RCT) double blind, parallel group, placebo controlled trial design". While not stated, additional data that would strengthen the evidence base from RCTs is dose response evidence (efficacy), and data that explains a mechanism(s) of action. It is self-evident that any dose recommended has to be accepted by the scientific community and the FDA. This additional information would strengthen the proposal from a company. The recommendation to consider "where" research is published is good, that is in a peer reviewed journal versus personal monologues. The statement made that scientific abstracts provide reasonably good evidence, but not necessarily definitive, given the lack of detailed information included is an excellent point.

The documentation needed to substantiate claims is not clearly specified, and this could lead to abuse by manufacturers. To alleviate this problem, we suggest that each section provide both good and bad examples of meeting each criterion. In the proposed document, some sections provide only bad examples.

The FDA suggests that consumer testing may be useful to determine consumer understanding of each claim in context. This is not required by FDA. However, the AHA Nutrition Committee recommends that consumer testing be recommended more strongly. This should not be a huge burden to companies who are applying for a dietary supplement claim. It will markedly strengthen their application, given that all of the science is in place. It is very important to demonstrate that the claim made by industry is clearly understood by the consumer. Consumer testing can provide information germane to the FDA proposed requirement that industry substantiate both the express statements and their implied meanings.

Relative to the NOA (b) we recommend that any company submitting a proposal for dietary supplement claims must acknowledge potential adverse effects of different population groups, including nutrient-nutrient interactions, as well as drug-nutrient interactions since many coronary patients are taking multiple drugs. This latter recommendation is particularly relevant to antioxidants. Specifically, companies should address potential adverse effects of different antioxidant cocktails in patients taking different medications for the prevention and treatment of coronary heart disease patients.

Demonstration of relative safety is only required for new ingredients, but not of ingredients marketed previously. We are concerned that this may not be sufficient to ensure the safety of new formulations of multiple ingredients that may have not been tested in combination. There is a suggestion that there is a lack of standard, and insufficient rigor in the procedures for demonstration of safety. The current penalties for failure to follow procedures for registration of new ingredients seem insufficient to be a significant deterrent. It is not clear from the proposal whether ingredients currently being included in supplements (and thus not subject to new ingredient procedures) are subject to different criteria for substantiation of efficacy.

In conclusion, the AHA Nutrition Committee applauds the FDA for its efforts to demand scientific rigor from dietary supplement companies attempting to make health claims.

Sincerely,

Nutrition Committee
American Heart Association

Please remember the American Heart Association in your will.