

January 10, 2005

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

**Re: Comment; Docket No. 2004D-0466; Draft Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act**

Dear Sir or Madam:

The Grocery Manufacturers of America (GMA)<sup>1</sup> appreciates this opportunity to offer comments on the above-reference draft guidance document relating to substantiation of structure/function claims for dietary supplements. The Federal Food, Drug, and Cosmetic Act has always permitted structure/function claims for conventional foods and the Food and Drug Administration has made important gains over the past decade in recognizing that these types of claims appearing on food labels can provide useful information to consumers in making informed purchasing decisions. GMA, therefore, anticipates that the draft guidance will similarly inform the agency's review of structure/function claims that appear in conjunction with conventional food products as well.

GMA applauds FDA's initiative in setting forth the amount, type and quality of evidence that FDA recommends a manufacturer possess in support of a structure/function claim. Such claims, whether appearing on the label of a dietary supplement or conventional food product, are useful to

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<sup>1</sup> GMA is the world's largest association of food, beverage, and consumer product companies. Led by a board of 46 Chief Executive Officers, GMA applies legal, scientific, and political expertise from its more than 140 member companies to vital public policy issues affecting its membership. The association also leads efforts to increase productivity, efficiency, and growth in the food, beverage, and consumer products industry. With United States sales of more than \$500 billion, GMA members employ more than 2.5 million workers in all 50 states.

consumers only if truthful, non-misleading information is conveyed. This guidance will provide important information to dietary supplement marketers as to the expectations and requirements of the law in regard to claim substantiation. It is also important that FDA utilize the guidance in the context of taking appropriate enforcement action against marketers who utilize purported structure/function claims that lack adequate substantiation.

FDA is commended for modeling its approach to claims substantiation on the Federal Trade Commission's competent and reliable scientific evidence standard. FDA, of course, operates under statutory authority distinct from the FTC. Nevertheless, GMA believes that FDA should look to the FTC model of claims substantiation with respect to all of the types of claims that may be used to convey diet and health information via the food label.

GMA finds the many examples particularly valuable because the competent and reliable scientific evidence standard is not always well-defined in the absence of specific examples. The flexible approach suggested, whereby the level of substantiation is dictated by the nature of the claim, is properly a key guiding principle. The level and limitations of the underlying scientific evidence should dictate the manner in which the claim is framed. This flexibility maximizes the flow of information to consumers while at the same time ensuring that the claim as framed is properly substantiated.

The nature of the scientific evidence, and how it will be reviewed by FDA, has been addressed by FDA in other contexts (e.g., qualified health claims). It is important to make clear that there is a range of data and other information that may be appropriate in determining if a structure/function claim is substantiated. The FTC's 1998 comment to FDA on claims substantiation states: "As a general matter, the FTC considers well-controlled human clinical studies to be the most reliable form of evidence, but also takes into account other forms of research, including epidemiologic evidence, animal and *in vitro* studies in appropriate circumstances."

The several comment periods set to close in January, and other agency initiatives underway, provide FDA with an important opportunity to revisit and reframe its regulations and policies in a fashion that maximizes consumer access to diet and health information. GMA looks forward to continuing to work with FDA on such efforts. The draft guidance document appropriately recognizes that clear, flexible standards for claims substantiation are an important component of ensuring that the objectives of the Consumer

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Health Information for Better Nutrition Initiative launched by FDA in 2003 are realized.

Sincerely,

A handwritten signature in black ink that reads "Alison Kretser". The signature is written in a cursive style with a large, sweeping flourish at the end of the name.

Alison Kretser, MS, RD  
Director, Scientific & Nutrition Policy