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National Nutritional Foods Association

January 22, 2004

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: Docket No. 2003N-0496

To Whom it May Concern:

The National Nutritional Foods Association ("NNFA") is submitting these comments to the Food and Drug Administration ("FDA") in response to the November 25, 2003 Food Labeling: Health Claims; Dietary Guidance, Advance Notice of Proposed Rulemaking. 68 Fed. Reg. 66040.

NNFA is a trade association representing the interests of more than 5,000 retailers, manufacturers, suppliers and distributors of natural foods, dietary supplements and other natural products throughout the United States. NNFA appreciates the opportunity to comment on the questions posed by FDA regarding the regulation of qualified health claims on dietary supplements.

It is well known that Americans with a variety of health concerns are seeking to actively participate in their own health maintenance by using supplements.<sup>1</sup> In 2002, dietary supplements represented a \$18 billion industry<sup>2</sup>. Thirty percent of these Americans get their information about dietary supplements from books or magazines, while another nineteen percent attain information from health food stores.<sup>3</sup> Health claim statements are one available means of information consumers look to in order to gain accurate information about the supplements they choose to use.

FDA is requesting comments on how qualified health claims can best be regulated by FDA. The three options proposed are: (1) continue the current interim procedures and evidence-based ranking system established by guidance this past year; (2) mandate full notice-and-comment rulemaking as is required for unqualified health claims; or, (3) treat qualified health claims as outside of the Nutrition Labeling and Education Act (NLEA), which provided for health claims for foods, and enforce against

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<sup>1</sup> "Condition-Specific Supplement Markets," Nutrition Business Journal (November 2001).

<sup>2</sup> "Annual Industry Overview," Nutrition Business Journal (May/June 2003).

<sup>3</sup> NNFA, Consumer Survey on Supplement Usage, August 2000.

them in the post marketing environment pursuant to the general false and misleading standards of the Federal Food Drug and Cosmetic Act.

The interim procedures were articulated in two Guidances published this year outlining the process for submitting and evaluating petitions for qualified health claims: “Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements,” and “Interim Evidence-based Ranking System for Scientific Data.” In the second guidance, FDA outlined the process for systematically evaluating and ranking the scientific evidence for proposed qualified health claims. Specifically, FDA stated it will review the body of evidence for: (1) quantity (*i.e.*, the quantity of studies, number of individuals studied and generalizability of the findings); (2) consistency (*i.e.*, sufficient number of well-designed studies with consistent results and among studies that are less well designed); and, (3) relevance to disease risk reduction in the general population or targetted subgroup.

Based on this review, FDA will issue a ranking for each proposed claim that will determine the type of disclaimer required. The ranking system will classify proposed claims as “A,” “B,” “C,” or “D,” according to the quality and strength of the scientific evidence. The type of qualification/disclaimer required for a health claim *depends* on the ranking:

FDA Category	Strength of Evidence Required	Appropriate Qualifying/Disclaimer Language
A	high level of comfort that the substance/disease relationship is scientifically valid	NONE
B	Moderate/good level of comfort that the claimed relationship is scientifically valid	“Although there is scientific evidence supporting the claim, the evidence is not conclusive.”
C	Low level of comfort that the claimed relationship is scientifically valid	“Some scientific evidence suggests . . . however, FDA has determined that this evidence is limited and not conclusive.”
D	Extremely low level of comfort that the claimed relationship is scientifically valid	“Very limited and preliminary scientific research suggests . . . FDA concludes that there is little scientific evidence supporting this claim.”

NNFA believes that FDA should codify a modified form of Option 1 which would incorporate some of the procedures summarized above. This Option benefits industry, consumers, and FDA because of its fast timeframe and flexibility – both of which are necessary in an environment where the science is evolving every day.

Option 1 provides a quick response by FDA and the ability of a manufacturer to revisit the qualified nature of the health claim once additional science is developed. The process allows FDA to review the claim in advance of it being marketed, but also provides an opportunity for scientists from the government, industry and non-governmental groups to evaluate the state of the science. Finally, it provides the manufacturer with a position

from FDA – an enforcement discretion letter – to use to educate consumers and customers about the claim. All of these attributes are very positive for industry and FDA alike.

This Option also provides motivation to manufacturers to continue developing science on dietary supplement ingredients in order to obtain qualified health claims, with the possible goal being an unqualified claim at some point. This may also encourage public-sponsored research to further investigate qualified health claims, since they will gain a measure of credibility by virtue of having gone through some review process.

The establishment of the proposed evidence-based system for dietary supplement health claims will help keep consumers abreast of emerging science on nutrition and disease prevention, even when the science is not to the level of “significant scientific agreement” as required for absolute health claims. It will allow the consumer to choose, based upon available knowledge as fully and accurately disclosed on the label, whether to purchase and use the product.

However, NNFA has one proposed modification to Option 1. NNFA believes that the standardization of disclaimer language, as set forth in the chart on the previous page, is not helpful. In fact, it has the contrary effect of being so repetitive and overused as to be ignored by consumers. Rather, each disclaimer should be tailored to the specific facts of the science supporting the claim under review, and be modified as necessary depending on how the science develops.

The adoption of three defined phrases to be applied across the board depending on the level of science is not valuable to consumers or industry, and does not provide a benefit to FDA either. Disclaimers are utilized to appropriately qualify a particular factual statement. They should be fact dependent, and not pushed into a mold. The Federal Trade Commission, which frequently recommends disclaimers, has not adopted standard disclaimer language to use in set scenarios based solely upon levels of science. FDA should not either.

This flexibility with disclaimer language would also address the use of the term “may” which is of concern to FDA – if each claim is tailored to the general state of the science, the use of the term “may” could be appropriate in some instances, but not all. In other situations, it may be more appropriate to phrase a claim such as “(nutrient) has been shown to play a role in prevention of (disease) in certain individuals”.<sup>4</sup>

NNFA agrees with FDA that Option 2 will be too restrictive and time consuming. It will not provide any incentive for companies to pursue health claims in any fashion, particularly in light of FDA’s reluctance to approve health claims. This Option will destroy companies’ First Amendment rights to make appropriately qualified health claims as provided for in the *Pearson* cases.

The third Option is equally unworkable. It would provide no assurance to a company that claims would be acceptable, and no guidelines within which to develop

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<sup>4</sup> As a note, if FDA does determine to adopt the disclaimers standardized above, each qualification should be premised on the finding that “FDA has concluded that”; such language should be added to the level B disclaimer in the chart.

claims language. For companies developing and supplying ingredients, it would not provide any assurance that their products could be sold as contemplated. Moreover, in this time of restricted funds, to force FDA to litigate to assess the validity of a claim, and resort to “a battle of the experts” at trial, is unreasonable.

For these reasons, NNFA respectfully suggests that FDA consider a modified version of Option 1. We appreciate the opportunity to participate in this rulemaking.

Respectfully submitted,

A handwritten signature in black ink that reads "David Seckman". The signature is written in a cursive, flowing style.

David Seckman  
Executive Director