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December 27, 2006

Docket #: 2002P-0122  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

**RE: Final Comments with Regards to the Public Hearing Titled: Conventional Foods Being Marketed as “Functional Foods”**

First of all, I would like to thank the Food and Drug Administration (FDA) for the opportunity to speak and applaud their efforts in encouraging a dialogue between all interested parties in the natural products community: suppliers (manufacturers and distributors); retailers; consumers and regulatory agencies. For those unfamiliar with the Natural Products Association (formerly the National Nutritional Foods Association (NNFA)) we were established in 1936 and are the oldest and largest non-profit 501(c) (6) association whose mission is to advocate for the rights of consumers to have access to products that will maintain and improve their health and for the rights of our members to sell those products. Our diverse membership, from the smallest health food store to the largest natural products manufacturer, encompasses all segments of the natural products marketplace; dietary supplements, natural and organic foods, natural health and beauty aids, raw material suppliers as well as functional foods. The Natural Products Association is pleased to participate in this hearing and would appreciate the opportunity to participate in any upcoming FDA workshops or meetings at which this subject would be discussed further.

In reference to the document released on October 25, 2006 regarding this hearing we wish to comment on a few aspects of the discussion on functional foods. Our experience tells us that natural products consumers, who research indicates tend to be better informed than the average shopper, are the first wave of buyers of innovative health products such as functional foods. The expansion and growth of functional foods to mass market, coupled with the increased availability of health information, often makes for unbalanced and provocative media attention, causing undue concern regarding the appropriate regulatory checks and balances.

Before the discussion regarding any new regulatory category can move forward, the current regulatory climate, and its features, both positive and negative, must be clearly presented and understood by all interested parties.

Regarding the current regulatory climate of functional foods we would like to reiterate the point made in the docket that dietary supplements have their own detailed regulatory category as a result of the Dietary Supplement Health and Education Act of 1994 (DSHEA) and should therefore not be considered for inclusion in any future regulatory discussion of functional foods. However, in moving the discussion forward on functional foods it may be wise to examine the intent of DSHEA, to balance consumer protection with consumer access, and how that may apply to functional food products. Balance safety, not efficacy, with access. The current food safety regime works, and has allowed Americans safe access to the greatest food supply in the world. Both FDA and the Federal Trade Commission (FTC) have

increased enforcement action against false claims and unsafe products, thus, demonstrating that the current system provides these agencies with adequate authority to take action when and where necessary. Additional regulation would simply be over regulation and result in limited access to products that may provide a health benefit beyond the nutritive value. The solution is not more regulation, but rather stronger enforcement of current food safety and fraud laws (i.e. 403(a) FTC section 5, and FDA misbranding provisions) to address problems that may exist in the current marketplace. In addition, there are questions that may require some answers to avoid any future confusion, or at a minimum, direction. Guidance regarding intended use and how intent can be determined on an ingredient specific basis, serving size and/or ingredient concentration, as well as dialogue on what exactly a "conventional" food matrix may or may not be, seem central to the discussion. We believe clear guidance helps to establish a level playing field for all products considered in the discussion.

As stated in the docket "under *Nutrilab v. Schweiker* (713 F.2d 335 (7th Cir. 1983)), structure/function claims on the label or in labeling of conventional food make the product a drug if they promote the product for a structure/function effect (e.g., blocking the digestion of starch) that is unrelated to the product's "food" attributes of taste, aroma, and nutritive value. FDA has interpreted this court decision to limit structure/function claims for conventional foods to claims about effects that derive from the taste, aroma, or nutritive value of the food or food ingredient that is the subject of the claim." We wish to encourage expanding structure/function claims to functional foods where the ingredient (i.e. GRAS for supplements), concentration of ingredient and food matrix (i.e. bars, beverages) is/are appropriate, we believe it will provide more good information to the public to make decisions, but to do so then all the ingredients and amount(s) of those ingredients needs to be spelled out on the label in the same manner as supplements so there is a balance between dietary supplements and functional foods, especially to compare ingredients in the marketplace. Why should a manufacturer of functional foods be limited in providing the consumer information on the benefits outside of nutritive value that the "Functional Food" may offer? *Pearson v. Shalala* required FDA to accept Qualified Health Claims on foods, because of the First Amendment. Why wouldn't that be applicable to structure/function claims where the science exists to support such claims? Because commercial speech, including advertising, is a valuable source of information to consumers, the Supreme Court has not upheld approaches that restrict speech; the government would first have to consider whether other approaches, such as increasing nutritional education or self-regulation, would not be more applicable to addressing functional foods.

The FTC and FDA also might wish to learn more about our association's commitment to truthful labeling and self-regulation. Supplier members who manufacture dietary supplements under their own label are required to be members of the Natural Products Association's TruLabel program. More than 23,000 product labels are currently registered as part of the TruLabel program. Member companies are required to pay for randomly monitored, independent laboratory tests of their products. Should a test reveal a product or ingredient deficiency, the member company is contacted and given a brief period to correct the product or label. A company that fails to comply may potentially be expelled from membership, and would be unable to exhibit at our annual convention and trade show, Natural MarketPlace. This is just one example of many creative, innovative and effective industry self-regulatory initiatives.

One issue that was not addressed in the docket was the Good Manufacturing Practices (GMP) of functional food products. While GMPs and extensive guidance are available on the manufacturing practices of foods, at the time this document was submitted the final rule regarding the GMP of dietary supplements had not yet been released from the Office of Management and Budget (OMB). Once the dietary supplement GMP rule does become final, where do products containing "Supplement" Ingredients in "Conventional Foods" reside with respect to manufacturing practices? Will the agency offer additional compliance guidance and regulation as they do with infant formula (7321.006) and medical foods (7321.002)? If manufacturers of dietary supplements or dietary ingredients are required to meet a more stringent GMP standard, it is only logical that the dietary ingredients responsible for any claim in functional foods should have to meet the same standard. Guidance regarding how to mix the food GMP's with the dietary supplement GMP's for functional foods, when the dietary supplement GMP's become final will be very beneficial to all stakeholders. We believe that GMPs are part of the answer as well, offering appropriate consumer protection.

Going forward, the Natural Products Association reiterates its interest in partnering with FDA, FTC and the US government to improve the quality of the products and marketing practices impacting the health of

our nation. We respectfully ask to be given the opportunity to comment and/or participate in any further action or discussion of functional foods.

Very truly yours,

A handwritten signature in blue ink that reads "Daniel Fabricant". The signature is written in a cursive style with a light blue background behind the text.

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