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**FDA CONFERENCE ON FUNCTIONAL FOODS
PRESENTATION OF STEVEN SHAPIRO
ON BEHALF OF HANSEN NATURAL CORPORATION**

DOCKET NO. 2002P-0122

DECEMBER 5, 2006

My name is Steven Shapiro. I am a partner in the New York law firm of Ullman, Shapiro & Ullman and I am here today speaking on behalf of Hansen Natural Corporation of Corona, California. Hansen develops, markets, and sells various foods in beverage form, as well as energy dietary supplements in liquid form.

Hansen believes that there is not a current need for a regulatory definition for the term “functional food” or for a new regulatory approach to evaluate the safety of ingredients. Hansen believes that the current regulatory scheme is more than adequate for this task.

If, however, the agency decides to create a definition for “functional foods” and an accompanying regulatory scheme, it should be done with one purpose in mind – to find a way to allow companies to continue to better educate consumers about the benefits of the foods and the ingredients in those foods that they consume. Hansen objects to any changes in the laws or regulations with an objective of limiting the amount of information that could be provided to consumers.

Certainly, in large part, the reason that we are here today is that we all recognize the public’s increasing demand for “functional foods” – which we take to mean foods that in themselves or through added ingredients have a health-promoting and/or disease-preventing property beyond the basic function of supplying nutrients essential for life. The public has recognized the benefits of dietary supplements and is now searching out every day foods that offer similar health benefits and well known health benefiting ingredients. By and large, these so-called, “functional foods” primarily include common herbs, including green tea, caffeine and caffeine sources, and essential fatty or amino acids -- all well known ingredients with long histories of safe use and consumption.

As to any question concerning the safety of “functional food” ingredients, Hansen respectfully submits that the current regulatory requirements applicable to conventional

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food ingredients, namely food additive and the general recognition of safety standard are more than adequate, as are requirements for new dietary ingredient notifications that apply to dietary supplement products. If any so-called "functional food" were to contain an unsafe ingredient, the FDA has more than sufficient authority to declare the product "adulterated" and to take enforcement action. Among other things, a food is adulterated, "if it bears or contains any poisonous or deleterious substance which may render it injurious to health."

As to allowing claims for these so-called, "functional foods", Hansen is strongly in favor of allowing the public to receive what it clearly wants and what is in its best interest to have – more information – not less – on food products and the health benefiting ingredients that they contain.

There is, therefore, no rational argument to be made for restricting the ability of companies to provide consumers with truthful, non misleading substantiated information about food products and ingredients, including information about common well known historical usage. Indeed, the principles of commercial free speech demand this. For this reason, Hansen would strongly support expanding the current requirement of nutritive value for conventional food structure/function claims to include claims for "the provision of physical or physiological effects that have been scientifically documented or for which a substantial body of science exists." Here too, the FDA has more than ample authority to regulate products and to take strong enforcement action – the Food and Drug Act permits the FDA to take enforcement action against any misbranded food, defined in part, as a food where "its labeling is false or misleading in any particular." In addition, the Federal Trade Commission has the ample authority to take enforcement action against companies that advertise foods with false, misleading and/or unsubstantiated claims.

Hansen would also not oppose a requirement that notifications to the FDA for the use of structure/function claims for conventional foods be required, as is currently the case for dietary supplements.

Finally, Hansen is concerned that this hearing may be sought to be used by some as an attempt to have the agency promulgate regulations that will restrict the sale of functional foods or will negatively affect the sale and marketing of dietary supplements that resemble conventional foods.

The Federal Register notification for this meeting stated that "for the purpose of this hearing, we are not considering dietary supplements to be encompassed by the term functional foods." Dietary supplements have their own detailed regulatory framework prescribed by Congress in the Dietary Supplement Health and Education Act of 1994."

DSHEA permits dietary supplements to be similar to conventional foods in composition and form, so long as the products are identified as "dietary supplements", bear Supplement Facts tables when required, and are not represented for use as a conventional food, or as the sole item of a meal or the diet.

There are beverages, such as sodas, that are conventional foods that may quench the thirst and have no other purpose and there are products that are correctly labeled as dietary supplements whose purpose is not to quench thirst, but are intended to provide other benefits, such as providing energy by delivering dietary ingredients in a convenient liquid form.

Clearly, one of the purposes in DSHEA in permitting dietary supplements to outwardly resemble conventional foods was so that we would not have the arbitrary distinctions that existed before DSHEA. It would defy logic for example, to draw a distinction between an energy dietary supplement in powder form to be added to 16 ounces of water and a product correctly labeled as a dietary supplement but subject to a different classification and regulatory scheme merely because it is sold in the constituted form in a 16 ounce bottle with the water or other liquid already added.

Along these same lines, it is illogical that under the current regulatory schemes for foods and dietary supplements that the agency's focus is frequently on arbitrary distinctions -- sometimes based on a single word on a product label -- whether a product is a food or a dietary supplement. There is nothing to suggest any real safety concern with functional foods. Hansen submits that the FDA should be focusing its attention and limited resources on how it can create a means for companies to best be able to communicate valuable truthful, non misleading and substantiated health information about all products, both food and dietary supplements, to consumers -- valuable information that consumers want and should be entitled to.