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Subject: Conventional Foods Being Marketed as "Functional Foods;  
Public Hearing; Request for Comments.

The purpose of this correspondence is to offer comments on the responsibility of the U.S. Food and Drug Administration (FDA) to insure that all foods, but, specifically foods that could be designated as functional foods, are safe, secure, sanitary, wholesome and properly labeled.

Foods nourish! Foods nourish by supplying *essential nutrients* and *energy*. The common problems associated with poor nourishment, which leads to poor health are: 1) not getting enough of the most essential nutrients; 2) getting too much sodium (an essential nutrient), cholesterol, sugar, fat and most important; 3) too many calories. Today, the emphasis is not on marketing foods that provide essential nutrients for growth, development and maintenance, but on marketing foods that promote and sustain health. Health is simply defined as the reduced incidence of disease or freedom of disease; a healthy state of being. Among all forms of available foods, which are commonly referred to as conventional foods, there are some foods that can be singled out, as foods with a function, as having health-promoting properties; functional foods.

In the U.S., it is often taken for granted, but with reasonable assurance that the food supply is safe. While Americans are cognizant of the need for a wholesome (nutritious) daily diet, this might not be their primary focus. The consumer is hearing more about the health-promoting benefits of particular foods; commonly called functional foods. Suggestions for how these functional foods can be referenced or highlighted

by (food) companies, how to protect the interests of the consumer, and how the FDA can insure the safety and food labeling of functional foods are offered in this letter.

While the U.S. Federal Food, Drug, and Cosmetic Act does define the term food, it does not define "conventional foods," or "functional foods." "Food" is defined to mean: (1) articles of or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. Since the law does partially define a dietary supplement, as a component that is "not represented for use as a conventional food" there appears to be some commonality between the terms "foods" and "conventional foods". However, it seems prudent for the FDA to consider a definition of functional foods, and simultaneously to establish a definition for conventional foods by using the existing definition for food.

A commonly used description or definition of a functional food is "food or food ingredients that may provide a health benefit beyond the traditional nutrients it contains" (U.S. Institute of Medicine (IOM), J. ADA 1995, 95:493-496). Other more inclusive definitions of functional foods have been suggested, most notably that offered by the Institute of Food Technologists (IFT, 2005). The simple definition offered by the IOM is preferred. For purposes of this hearing, December 5, 2006, by the FDA to discuss issues stated in the purpose of this correspondence, ["functional foods" are described "to mean conventional foods that are marketed as functional foods and we are using the term "ingredient" to mean "functional food" ingredients that may have a purported health benefit and may be the subject of a label statement about this purported health benefit, whether the ingredient is new to the food supply.]

In addition to establishing a description (definition) of functional foods, the FDA should separate and use a more specific term than "ingredient" to mean the (bioactive) functional food ingredient(s) that may have a purported health benefit(s). The term "nutraceutical" is suggested. The (food) industry-companies, wanting to market a conventional food as a functional food, have two, currently FDA approved, options to help identify and market a functional food. The FDA allows for a "quantitative statement" on a food label for a compound or bacteria (and yeast) in foods other than those nutrients allowed on a food label, for example "contains 500 mcg of Lutein per serving"; "contains  $10^8$  cfu Lactobacillus per serving". Secondly, the FDA allows for structure/function claims to complement and be associated with the compound cited in the "quantitative

statement", for example: "promotes eye health," "promotes a healthy intestine." This is offered as a suggestion to give the (food) industry-companies the opportunity to identify and separate a "functional food" from the wide array of "conventional foods"; all functional foods are considered, first, to be conventional foods. Therefore, the current food labeling options are available for a food company to provide the consumer with the initial information that the food contains a nutraceutical (a potential health promoting ingredient) and its amount. And, if sufficient information is deemed appropriate and available, a structure/function claim can be made.

It is acknowledged that if only a "quantitative statement" is made on a food label such as, "contains 500 mcg of Lutein per serving", "contains  $10^8$  cfu Lactobacillus per serving", it is up to the (food) industry-company to identify the potential health importance of the nutraceutical(s) in the functional food and indicated on the label. Also acknowledged are the differing amounts and types of scientific data needed by the industry-company to substantiate and transition from a "quantitative statement" to a "structure/function claim" to a "health claim" for a functional food and or its bioactive nutraceutical component.

Functional foods are conventional foods that may be fortified, enriched or enhanced with essential nutrients and or nutraceuticals. While the functional food has nutritive value in providing some essential nutrients and energy, the bioactive ingredient(s) itself, the nutraceutical(s), may not have proven nutritive value in the traditional sense. Functional foods should not include dietary supplements or extracted-concentrated nutraceuticals not found in a conventional food. The restriction that labeling statements about the health benefits of a functional food must be limited to benefits that derive from its "nutrient value" should be revised. Hopefully, the (essential) nutrient value of a conventional food can be separated from its potential to be described as a functional food.

Stated again, foods nourish by supplying essential nutrients and energy. There are 41 essential nutrients that the FDA can consider as providing or contributing to the "nutritive value" of foods. The nutritive value of foods in the form of energy is provided by digestible carbohydrates, protein and fat, and to a limited extent dietary fiber. A food claimed or marketed as a functional food is a conventional food and therefore one or more essential nutrients and some form of energy containing macronutrient would be present. An isolated

nutraceutical(s) is not an essential nutrient, until proven to be essential through scientific study. It is realized that it may take years or decades to demonstrate the health promoting effects of a functional food or nutraceutical. While the FDA needs to define the meaning of the "nutritive value" of a food, whether the food is called conventional or functional, it is recommended that mention of the potential health benefits of a functional food not be dependent on the "nutritive value" of the bioactive substance (nutraceutical).

To allow a statement on a food label that a food is specifically a functional food is a challenge. While the concept of functional foods can be a tremendously enlightening health experience for the consumer, and a marketing opportunity for the (food) industry-company, the scientific data to support the many suggested health benefits is often not readily available for such foods. It should be the responsibility of food industry-company to suggest and find better ways to market and communicate with the consumer about the health benefits of a functional food. Use of "quantitative statements" and possibly a "structure/function claim" are offered as appropriate first means to provide truthful information to the consumer. Although the comments offered here are intended to promote the marketing and labeling of functional foods, the consumer should be vigilantly protected and assured that they are not receiving misleading and or incomplete health advice on food labels. The FDA should continue to generally regulate conventional foods that are marketed as functional foods under the same set of regulations as conventional foods. However, it is realized that this may create some severe restrictions on the marketing of a functional food.

The isolation of a nutraceutical(s) from a functional food and the addition of this nutraceutical to a processed or unprocessed food, for purposes of health promotion, should require specific evidence of safety (i.e., either a food additive approval or a GRAS notification on file) and labeling with a "quantitative statement". If a structure/function claim is to be made for a functional food created by the addition of a nutraceutical, a notification letter to the FDA with available documentation supporting the purported benefits should be submitted. In addition, if a nutraceutical compound(s) is added to a conventional food, to increase that compound's level in the food, the word "added" or some similar notation should be used with the quantitative statement, such as "contains added Lutein, 1000 mcg per serving". Consumers should be provided with enough information to know that they are consuming a specific amount

of nutraceutical that is either naturally occurring in a functional food or a specific amount that has been added to the food.

The use of a "quantitative statement" for a nutraceutical is considered different than a "nutrient content claim". Until a nutraceutical is determined to be an essential nutrient, it would not qualify for a "nutrient content claim". However, with significant scientific agreement (SSA), a nutraceutical could qualify for a health claim. For example, stanol esters, a type of nutraceutical, have been granted a health claim based on SSA. However, until such SSA is available for nutraceuticals, a nutraceutical with at least a minimum of scientific data could bear only a structure/function claim. It is recognized that a functional food could have a permissible structure/function claim without identification of any bioactive ingredient (a nutraceutical) upon which the claim is based.

The IFT suggestion that Generally Recognized as Efficacious (GRAE) panels need to be convened to evaluate labeling health claims about a functional food or nutraceutical is strongly supported.

While suggestions are sought by the FDA on how to best ensure the safety of functional foods and their proper labeling, it is highly recommended that the FDA must become more active in monitoring existing regulations on the labeling of conventional foods.

There are two important criteria for an FDA approved health claim. First, the amount of a substance must be established, and secondly, this amount must be scientifically demonstrated to bring about the desired change in health promotion. Stanol esters are not essential nutrients, they are a dietary ingredient, but have been shown to be effective "substances" in lowering blood cholesterol levels. There is an authorized health claim for stanol esters.

The FDA should provide guidance to the food industry on safety-related information and evidence need to support structure function claims for functional foods. Conventional foods selected or classified as functional foods do not need a safety evaluation. Extraction and/or concentration of nutraceutical(s) to enhance dietary intake of the nutraceutical(s) should require a safety summary in the form of at least a GRAS notification to FDA. The IFT proposed employing Generally Recognized as Efficacious (GRAE) panels to expedite

the evaluation of health claims and qualified health claims. A GRAE panel as a volunteer effort may also provide the (food) industry-company the opportunity to have a well reviewed structure/function claim.

Respectively submitted,

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