FDA Announces Public Hearing on Conventional Foods Being Marketed as "Functional Foods"

FDA recently announced that it will be holding a public hearing on the regulation of certain conventional foods that are being marketed as “functional foods.” The agency states that the purpose of the hearing is for FDA to share its current regulatory framework and rationale regarding the safety evaluation and labeling of these foods, and to solicit information and comments from stakeholders on how the agency should regulate these foods under the FDA’s existing statutory authority. The hearing will be held on Tuesday, December 5, 2006, from 9 am to 4:30 pm. The Federal Register notice sets forth general background on this issue and lists specific questions on which FDA seeks comment. Written comments may be submitted until January 5, 2007. Interested parties may also request an opportunity to make an oral presentation at the hearing, which request must be submitted by November 14, 2006.

While this hearing is intended as an initial dialogue, all companies interested in what has become known as “functional foods,” as well as companies with interests in food and dietary supplement claim substantiation issues more broadly, should seriously consider filing comments with FDA. The agency has raised questions as to whether significant changes should be made in its regulatory scheme governing “functional foods,” including whether it can and should impose considerable new requirements on these products, such as additional scrutiny of ingredients used and premarket clearance of claims made. The following summarizes the general background on this issue and the particular questions on which FDA seeks comment.

I. Background

A. Purpose of the Public Hearing

FDA recognizes that the food industry has recently developed and marketed foods referred to as “functional foods.” As there is no formal definition of this term, FDA references the definition in the March 24, 2005 report by the Institute of Food Technologists (“IFT”) entitled “Functional Foods: Opportunities and Challenges” (“IFT Report”). There, IFT defined “functional foods” as foods and food components that provide a health benefit beyond basic nutrition (for the intended population). These substances provide essential nutrients often beyond quantities necessary for normal maintenance, growth, and development, and/or other biologically active components that impart health benefits or desirable physiological effects.

2 You may register to attend the hearing at http://register.grad.usda.gov/conferences/fdahearing/.
While the IFT included in the “functional foods” category conventional foods, fortified, enriched, or enhanced foods, and dietary supplements, FDA clarifies that for purposes of the upcoming hearing, the agency is not considering dietary supplements to be encompassed by the term, “functional foods,” largely because dietary supplements have their own detailed regulatory framework prescribed by Congress in the Dietary Supplement Health and Education Act of 1994 (“DSHEA”) and in FDA’s implementing regulations and guidance documents.

While FDA states that the agency is confident that the existing provisions of the Federal Food, Drug and Cosmetic Act (“FDCA” or “Act”) are adequate to ensure that conventional foods being marketed as “functional foods” are safe and lawful, the agency believes that it would be in the best interest of public health to begin a dialogue with industry, consumers, and other stakeholders regarding the regulation of these products.

B. Reports and Recommendations Regarding “Functional Foods”

In the Federal Register notice, FDA describes the current statutory and regulatory framework governing the safety of food ingredients and the labeling of food. The agency also addresses the following reports and recommendations that have been issued regarding “functional foods.”

1. GAO Report

The Government Accountability Office (“GAO”) issued a report in July 2000 entitled, “Improvements Needed in Overseeing the Safety of Dietary Supplements and ‘Functional Foods’” (“GAO Report”). That report recommends that Congress amend the FDCA to require “functional food” manufacturers to: submit premarket notification to FDA concerning the use of ingredients that companies have determined are safe; submit notification to FDA regarding the use of structure/function claims on such foods; and use disclaimers of FDA approval on “functional food” labels containing structure/function claims.

2. ILSI Report

The Functional Foods Committee of the International Life Sciences Institute (“ILSI”) issued a report in August 2000 entitled “Health Claims on Functional Foods – Proposals on Scientific Substantiation and Regulatory Systems.” That report discusses recent developments in the marketing of “functional foods,” and highlights factors to consider when conducting a clinical study in support of a health claim in order to appropriately use the data gathered during the study.

3. IFT Report

The March 2005 IFT report noted above raised a number of issues and recommendations regarding “functional foods.” These include recommendations that FDA establish, by regulation, a definition of, and labeling requirements for, “functional foods”; that FDA should not limit substantiated claims for “functional foods” to only those benefits derived from the food’s nutritive value; and that research into “functional foods” be stimulated using incentives to the food industry.
IFT also recommends that companies wishing to make claims for “functional foods” convene panels of independent experts qualified to evaluate the efficacy of the food or component under consideration. The findings of such panels would be submitted to FDA under a process similar to the notification program currently used for generally recognized as safe (“GRAS”) substances. FDA would have 90 days to object to the use of the notified label claim, and the claim would be permitted if that time period expired without objection from the agency. FDA acknowledges that the FDCA limits the agency’s ability to accept this recommendation with regard to health claims and nutrient content claims. As noted below, however, FDA does ask for comment as to the weight it should give to the evaluations of non-governmental groups when evaluating the strength of science supporting a claim.

4. CSPI Citizen Petition

The Center for Science in the Public Interest (“CSPI”) submitted a citizen petition in March 2002 requesting additional FDA regulation of “functional foods.” CSPI asks FDA to require companies to notify the agency regarding the use of “novel ingredients” prior to marketing foods containing such ingredients and to notify the agency within 30 days of marketing a conventional food bearing a structure/function claim if the food contains a “novel ingredient.” CSPI also asks FDA to require such foods to bear disclaimers on the label akin to those currently required for dietary supplements bearing structure/function claims.

II. Questions for Discussion and Comment

FDA raises a number of questions under three broad headings: food ingredients, food labeling, and the overall framework for foods marketed as “functional foods.” These questions are summarized briefly below. For each, FDA asks commenters to identify the scientific and legal basis for their positions.

A. Food Ingredients

1. Is there a need for a regulatory definition and a distinct regulatory approach to the evaluation of the safety of ingredients added to “functional foods”?

2. Should companies that market ingredients for addition to “functional foods” be required to notify FDA prior to introducing the ingredients into interstate commerce?

3. What types of data and information would be appropriate to demonstrate that ingredients added to conventional foods being marketed as “functional foods” meet the safety standard of “reasonable certainty of no harm”?

4. How could the agency partner with interested stakeholders regarding the development of appropriate recommendations or other information regarding the safety assessment of ingredients added to “functional foods”?

3 IFT uses the phrase “Generally Recognized as Efficacious” (“GRAE”), which is potentially controversial because it echoes a comparable phrase used in drug regulation.
B. Food Labeling

1. If FDA’s statutory authority permits, should the agency require food companies to notify it within 30 days of marketing a conventional food bearing a structure/function claim and to include the label disclaimer currently required on dietary supplements making such claims?

2. Within FDA’s statutory authority, how (if at all) should the agency utilize the findings of non-governmental groups in support of health claims, nutrient content claims, and other labeling claims about the effects of a “functional food” or ingredient? Should FDA institute a premarket notification process for review of the scientific evidence for structure/function claims for “functional foods” and ingredients?

3. FDA states that the agency currently takes the position that structure/function claims for conventional foods must be limited to claims about the effects that derive from the taste, aroma, or nutritive value of the food or food ingredient that is the subject of the claim. Does this legal interpretation adequately allow for claims in the labeling of “functional foods”?

4. Should FDA provide incentives to manufacturers to conduct further research on emerging substance/disease relationships?

C. Overall Framework for Foods Being Marketed as “Functional Foods”

1. Can the conventional foods being marketed, or to be marketed in the future, as “functional foods” be adequately addressed through the current regulations for food additives, GRAS substances, and labeling claims?

III. Recent European Union Regulation on Nutrition and Health Claims on Foods May Bear on FDA’s Consideration of “Functional Foods”

While a number of factors may have prompted FDA to call a hearing on “functional foods,” recent developments in the European Union (“EU”) may have contributed to the agency’s timing. On October 12, 2006, the European Council adopted the Regulation on Nutrition and Health Claims on Foods. The Regulation harmonizes the current divergent rules and practices in the EU and, overall, will result in stricter requirements for using nutrition and health claims in the EU. The concepts of “nutrition claim” and “health claim” are broadly defined and, for example, “nutrition claim” also covers claims relating to substances that are not nutrients but do have a nutritional or physiological effect. Such “nutrition claims” might parallel those made for products marketed as “functional foods” in the United States. Under that new Regulation, “nutrition claims” will be allowed only if they are listed in the Annex of the Regulation, which can be amended, and must comply with the conditions contained therein. Further, foods must in principle comply with a specific nutrient profile – to be established by the European Commission – or have only a single nutrient that exceeds the nutrient profile, in order for a claim to be allowed.

*In this Notice, FDA cites the regulatory definition of “nutritive value” at 21 C.F.R. 101.14(a)(3), where it is defined to mean “a value in sustaining human existence by such processes as promoting growth, replacing lost nutrients, or providing energy.” FDA has, however, expanded its concept of what constitutes a “nutrient,” starting with the agency’s treatment of dietary fiber and cholesterol under the Nutrition Labeling and Education Act of 1990 and more recently in its approach to plant stanols and sterols.*
Attorneys in Covington & Burling LLP’s European offices can provide greater detail regarding this new Regulation to those who may be interested, but for current purposes it is relevant to note that the upcoming FDA hearing and comment docket will be an appropriate place to urge the agency not to follow this narrow and restrictive EU model with respect to claims for “functional foods.”

Given the potentially significant questions raised by FDA, companies interested in what has become known as “functional foods,” as well as those interested in claims substantiation issues more broadly, should seriously consider filing comments with the agency. This firm has considerable expertise in this area and would be pleased to assist in the drafting of such comments.

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This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

- Eugene Lambert 202.662.5422 elambert@cov.com
- Clausen Ely 202.662.5152 cely@cov.com
- Sarah E. Roller 202.662.5563 sroller@cov.com
- Jeannie Perron 202.662.5687 jperron@cov.com
- Miriam Guggenheim 202.662.5235 mguggenheim@cov.com
- Heather Banuelos 202.662.5161 hbanuelos@cov.com

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