FDA Holds Public Hearing on the Regulation of "Functional Foods"

Key Issues Under Consideration Also Relate to Claims Substantiation Generally

On December 5, 2006, FDA held a public hearing on the regulation of “functional foods.” As set forth in the agency’s Notice, 1 described in Covington & Burling LLP’s November 10, 2006 Food & Drug E-Alert on this matter, the purpose of the hearing was 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 its existing statutory authority. In the Notice of the hearing, FDA had 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.

This memorandum provides a brief description of key issues discussed at the day-long hearing. The docket remains open for written comments until January 5, 2007. 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, given the significance of the potential regulatory options under consideration.

I. FDA Overview

FDA began by reiterating its starting position that the existing provisions of the Federal Food, Drug, and Cosmetic Act (“FDCA” or “Act”) and the agency’s implementing regulations are adequate to ensure that foods being marketed as “functional foods” are safe and lawful. The agency asked, however, whether guidance or other clarification is needed to help those marketing functional foods work their way through the regulatory regime. FDA addressed both the safety of “functional” foods and ingredients and the claims made for such products.

Dr. Laura Tarantino, Director of the Office of Food Additive Safety (“OFAS”) in FDA’s Center for Food Safety and Applied Nutrition (“CFSAN”), presented an overview of the statutory and regulatory scheme governing all substances that may be added to conventional food 2 as either food additives or substances generally recognized as safe (“GRAS”). She listed examples of food ingredients recently accepted by FDA as GRAS that could be deemed “functional” ingredients (rather than “technical” ingredients in the food product), including vegetable oil phytosterol esters, carrot fiber, and salmon oil, and advised that it is relevant to think about the range of substances dealt with under the current regime when considering whether there is a need to specifically address “functional foods” as a distinct category.

2 For purposes of this hearing, FDA did not consider 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.
Dr. Barbara Schneeman, Director of the Office of Nutritional Products, Labeling, and Dietary Supplements ("ONPLDS") at CFSAN, then presented an overview of the statutory and regulatory framework for the labeling of food, with a focus on the provisions of governing law prohibiting false and misleading claims. Notably, Dr. Schneeman commented that recent court decisions have found that FDA must consider consumer studies before finding a statement on a product label is misleading. She observed that the goals of the Nutrition Labeling and Education Act of 1990 ("NLEA"), which amended the FDCA, were to make information available to help consumers select foods that will help them achieve healthier diets and to encourage product innovation, while also protecting consumers from misleading claims. Dr. Schneeman described the categories of claims that may be made relating to health benefits of food: health claims (including qualified health claims), nutrient content claims, dietary guidance, and structure/function claims. She also noted that FDA’s fortification policy at 21 C.F.R. § 104.20 has also been relevant to many of the issues that have arisen with respect to "functional foods."

After these opening presentations by the agency, representatives from the scientific community, industry, and consumer groups spoke, followed by an opportunity for questions from an FDA panel. The following are the key issues discussed by these stakeholders.

II. "Functional Foods"

The definition, or need for a definition, of "functional foods" was much discussed, although all presenters agreed that all foods are "functional" (as is inherent in the food exclusion from the "structure/function" portion of the statutory drug definition). Generally, agency officials and industry representatives did not see a need for a uniquely-defined category of foods called "functional foods." Rather, they viewed current agency authority as wholly adequate to address this product category. The comments of various stakeholders supported more robust enforcement of existing law in this arena.

The Institute of Food Technologists ("IFT") proposed, in a March 2005 report entitled "Functional Foods: Opportunities and Challenges" ("IFT Report"), to define "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.

IFT also expressed its belief that a few changes in regulatory policies with respect to functional foods could benefit the public by allowing truthful and scientifically substantiated information about the health benefits of foods to be conveyed clearly and accurately. Other stakeholders, such as the Center for Science in the Public Interest ("CSPI"), focused more on the "functional" ingredients added to foods than on a separate category of finished food products, and urged additional regulatory scrutiny of such ingredients and food products.

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3 That panel consisted of Dr. Tarantino, Dr. Schneeman, other representatives from OFAS, ONPLDS, and FDA’s Office of General Counsel, and the panel chair, Michael Landa, Deputy Director of CFSAN.
A. Safety

Some concerns were expressed by stakeholders about the use of functional ingredients that may be derived from conventional food sources but are now being affirmatively added to other foods at levels higher than those in the foods in which the substances naturally occur. FDA responded that all food ingredients must be safe for their intended use, and that the current regulatory scheme would prohibit the use of ingredients in a new manner that is not either encompassed within the conditions of use specified in a food additive regulation or otherwise deemed GRAS.

B. Health and Functional Benefit Claims

1. "Nutritive Value"

Much discussion revolved around FDA’s current position that health or functional benefit 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. The agency asked whether this legal interpretation adequately allows for such claims in the labeling of “functional foods.”

Many stakeholders, both within and outside industry, responded that this approach is unduly limiting, and that claims should also be permitted for benefits provided by a food substance through its physical or physiological effect. IFT commented that the concept of “nutritive value” needs to be expanded to better reflect current science. Another commenter stated that FDA’s narrow approach is due to an erroneous reading of the court’s determination in *Nutrilab v. Schweiker*, for that court observed that consumers also choose food products, such as coffee or prune juice, for other reasons such as their physiological effects.

2. Claim Language

A range of comments were made regarding FDA’s approach to claim language, with some arguing that the agency has been too restrictive while others complained that it is too lenient. IFT and others expressed concern that in trying to avoid classification as a drug, some products bear claims that do not fully reflect the scientifically-substantiated health benefits of a food substance. For example, even where the evidence may show that a food substance can help lower cholesterol, FDA’s current policy for structure/function claims requires the claim to be limited to expressing that it may help retain already-normal cholesterol levels.

IFT also urged FDA to prohibit qualified health claims relying on “very limited and preliminary scientific evidence,” even where the claim language may accurately reflect the level of evidence. CSPI argued that qualified health claims are misleading to consumers and should not be permitted on conventional foods at all.

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4 FDA defines “nutritive value” to mean “a value in sustaining human existence by such processes as promoting growth, replacing lost nutrients, or providing energy.” 21 C.F.R. § 101.14(a)(3).

5 Note, however, that FDA has 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.

6 713 F.2d 335 (7th Cir. 1983).
Another question raised was whether to require a disclaimer for structure/function claims on conventional foods, comparable to that currently required for dietary supplements. FDA questioned whether it would have the legal authority to impose such a requirement.

Finally, a few commenters recommended that, where claims are made about a functional ingredient, FDA should require the label to state the amount of that ingredient per serving, so that consumers can better evaluate and compare foods.

III. Premarket Notification

A number of stakeholders recommended that FDA establish a system for premarket notification regarding functional foods and ingredients, although the proposed approaches differed, with some focused on safety of ingredients and others on claims of "efficacy."

CSPI asked FDA to require companies to notify the agency regarding the use of “novel ingredients” prior to marketing foods containing such ingredients, and recommended a safety evaluation modeled on the current premarket consultation process for foods developed through biotechnology. CSPI also asked FDA to require companies to notify the agency within 30 days of marketing a conventional food bearing a structure/function claim if the food contains a “novel ingredient.”

IFT proposed a premarket notification system for qualified health claims that would document the efficacy of the substance that is the subject of the claim. The approach would parallel the current GRAS notification process relating to the safety of a food ingredient. IFT suggested that third-party Generally Recognized as Efficacious (“GRAE”) panels could play a key role in providing evidence of consensus as to the efficacy of the substance, and that this proposed approach could help conserve agency resources in evaluating such claims and improve consumer confidence in such claims. IFT envisioned that such a premarket notification process would include industry incentives such as a period of exclusivity to use a claim.

FDA panelists raised questions about the agency's authority to implement these proposed approaches, including the provision of incentives such as exclusivity.

IV. Postmarket Surveillance

Both CSPI and IFT recommended potential requirements for postmarket surveillance, although these recommendations differed in a manner consistent with their distinct approaches described above. CSPI requested that FDA implement a system for post-market surveillance and adverse event reporting for safety issues relating to novel ingredients in functional foods. IFT recommended in-market surveillance to confirm the findings of pre-market assessments relating to the safety and efficacy of a functional food ingredient, as well as the accuracy and consumer understanding of claims about the substance. Again, FDA panelists questioned whether the agency has the legal authority to implement such recommendations.

7 While IFT’s proposal addressed qualified health claims, FDA noted that IFT’s recommendation to expand the concept of “nutritive value” to include physical or physiological effects could suggest that certain claims now considered structure/function claims could be deemed qualified health claims under the IFT approach.
V. Dietary Supplements

Although the hearing was intended to address only the regulation of conventional foods marketed as “functional foods,” a number of representatives from the dietary supplement industry and consumer groups commented that the current marketing of functional foods at times blurs the distinctions between such foods and dietary supplements. They argued that such functional foods are actually dietary supplements marketed as conventional foods to take advantage of the more lenient regulatory environment, and urged FDA to enforce a more level playing field or to more clearly regulate each product category.

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There are potentially significant issues raised by FDA and other stakeholders that may form the basis of future FDA action in the area of “functional foods.” Questions about safety, eligibility to bear a claim (e.g., physical or physiological effects), claim language, and the scope of FDA’s statutory authority, among others will directly impact any new regulation of “functional foods,” as well as affect the agency’s current regulation of conventional foods and claims. 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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