What may seem to be a dream marketing environment could be a regulatory nightmare for a company that does not contemplate the different legal requirements of each as it embarks on a new marketing campaign. This article will summarize the differences between these designations and explore some of the regulatory opportunities and pitfalls that come with the “functional foods” designation.

The terms “functional food,” “nutraceutical,” and “designer food” do not appear in the Federal Food, Drug, and Cosmetic (FD&C) Act nor in FDA regulations; however, they are alternative expressions that have become increasingly popular in health food and mainstream consumer markets to refer to foods that may provide health benefits beyond traditional nutrients. To better understand where these foods fall within the regulatory landscape, it is useful to turn to those food products that are defined under statute or regulation.
supplements in the form of tablets, capsules, etc., would not be considered conventional food; however, conventional food products such as cereals, food bars, and sports drinks could be described as dietary supplements if they are represented as something other than conventional food and meet the other DSHEA requirements (see further discussion below).

Dietary Supplement

A “dietary supplement” is defined under DSHEA as a product “intended to supplement the diet” that contains one or more of the following dietary ingredients: vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or concentrate, metabolite, constituent, extract, or combination of any ingredient described above (FD&C Act § 201(ff)(1)). As noted above, a dietary supplement also can be marketed in other forms, but, by statute, it must be labeled as a dietary supplement and cannot be “represented for use as a conventional food or as a sole item of a

Food

“Food” is defined in the FD&C Act as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article” (FD&C Act § 201(f)). In reviewing this definition, the US Court of Appeals for the Seventh Circuit stated that “the statutory definition of ‘food’ includes articles used by people in the ordinary way most people use food – primarily for taste, aroma, or nutritive value” (Nutrilab Inc. v. Schweiker, 713 F.2d 335, 338 [7th Cir. 1983]). This interpretation has been accepted by FDA and other federal courts.

Medical Food

“Medical food” is a distinct category of food that is specially formulated to be consumed or administered enterally (i.e., by mouth or through a tube or catheter), normally under the supervision of a physician, and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation (21 CFR § 101.9(j)(8)). A medical food is permitted to make claims that address a patient’s special dietary needs that exist because of a disease; but it is not authorized to bear claims to cure, mitigate, treat or prevent a disease, which are drug claims under the FD&C Act.

Conventional Food

The concept of “conventional food” is—to a large extent—an outgrowth of the Nutrilab case and, ultimately, the Dietary Supplement Health and Education Act of 1994 (DSHEA). The Nutrilab definition of food focused on its primary characteristics: taste, aroma, and nutritive value. With DSHEA, the concept of food was expanded to include dietary supplements. With this statutory change, tablets, capsules, powders, softgels, gelcaps, and liquids intended for ingestion could be considered food products. To distinguish these food products from those ingested primarily for their taste, aroma, and nutritive value, it has become useful to refer to the latter as “conventional food.” Interestingly, under DSHEA, dietary supplements in the form of tablets, capsules, etc., would not be considered conventional food; however, conventional food products such as cereals, food bars, and sports drinks could be described as dietary supplements if they are represented as something other than conventional food and meet the other DSHEA requirements (see further discussion below).
meal or the diet” (FD&C Act § 201(ff)(2)(B)-(C)).

Under DSHEA, a dietary supplement manufacturer is not required to obtain premarketing clearance from FDA if the ingredients have been marketed in the US before October 15, 1994. Additionally, dietary supplement ingredient claims are specifically excluded from the definition of a “food additive” (FD&C Act § 201(s)(6)). Thus, a product containing echinacea, kava kava, and/or St. John’s wort, for example, could be marketed in the US as a dietary supplement without FDA review or pre clearance of the product’s safety.

Functional Food

“Functional foods” have, to a large extent, grown out of industry’s desire to apply the claims and apparent regulatory flexibility available to dietary supplements to conventional food products. This term has been applied to a broad spectrum of products from herbal teas and soups to soft drinks and snack bars, but has no formal definition or clear regulatory framework. However, there is a general understanding that products described as “functional foods” tend to be conventional food products with health-promoting ingredients or components that go beyond their traditional nutritive value.

Notwithstanding this general understanding, from a regulatory standpoint, functional food products fall into the legal category defined above as “food.” As such, unlike dietary supplements, functional food ingredients must be either approved food additives or ingredients that are “generally recognized as safe” (GRAS) by qualified experts under the conditions of the intended use. Additionally, their labeling claims must be consistent with the general food provisions of the FD&C Act and its implementing regulations. These distinctions are important to keep in mind since they mean that products that contain the same dietary ingredients but are labeled as either dietary supplements or functional foods will have different safety and labeling requirements.

Safety

As recently as January 30, 2001, in a letter to manufacturers, FDA expressed concern over the “significant growth in the marketplace of conventional food products that contain novel ingredients, such as added botanical ingredients or their extracts that have not previously been used as food ingredients.” In this letter, FDA reiterated that “some of the herbal and other botanical ingredients that are being added to conventional foods may cause the food to be adulterated because these added ingredients are not being used in accordance with approved food additive regulations and may not be GRAS for their intended use.”

FDA has issued numerous warning letters to companies incorporating dietary ingredients widely used in the dietary supplement market into conventional food products. For example, in a warning letter to a juice manufacturer, FDA identified ingredients such as echinacea, grape seed extract, and gingko biloba as inappropriate food ingredients. The letter stated: “FDA has not issued a food additive regulation authorizing the use of these ingredients in food. Additionally, we are not aware of a basis for concluding that these ingredients are GRAS for use in conventional food.” In another warning letter, sent to a snack food company, FDA identified echinacea, gingko biloba, St. John’s wort, cat’s claw, kava kava and spirulina as inappropriate food ingredients in that they were not subject to an authorizing food additive regulation and the agency was unaware of a basis for concluding that they were GRAS.

While FDA, at this time, has taken no further enforcement action against these companies, the Center for Science and the Public Interest (CSPI) has submitted 13 letters to FDA as of July 2000 urging further action against such products under the adulteration and misbranding provisions of the FD&C Act. The General Accounting Office (GAO) also investigated FDA’s regulation of functional foods and issued a report in July 2000 entitled, “Improvements Needed in Overseeing the Safety of Dietary Supplements and ‘Functional Foods’” (GAO/RCED-00-156). In response, FDA indicated in its Center for Food Safety and Applied Nutrition (CFSAN) fiscal 2001 Program Priorities, that one of its “A” list goals is to “define boundaries among product categories,” in particular “ensuring that dietary supplement ingredients, when added to conventional food, are lawful.”

Thus, manufacturers of functional food products need to be cognizant of the different safety rules that apply to functional food products as distinguished from dietary supplements—at least until the term “functional food” is further defined by statute or regulation.

Labeling

As discussed under the dietary supplement section, a functional food potentially could be regulated as a dietary supplement product if it meets the requirements of DSHEA—most importantly, if it is labeled as a dietary supplement and not represented for use as a conventional food. However, a common fallacy is that a functional food can be bootstrapped into the dietary supplement category by simply adding traditional herbal and/or botanical ingredients and labeling the
product a dietary supplement. FDA has shown that it will look beyond the labeled representation to the intended use of the product.

The most well known examples of FDA looking beyond a product’s labeled representations in the functional food context are Benecol® and Take Control®. Both products contained phytosterols and originally were characterized as dietary supplement “margarine substitutes.” However, based on this description as well as prototype labeling promoting the product’s flavor and texture presented to FDA during a premarketing meeting, FDA stated that Benecol®, and similarly marketed products such as Take Control®, “while labeled as a dietary supplement, bears label representations that establish the intent of this product to do more than supplement the diet.”

As such, FDA stated that the marketing of the product as a dietary supplement “would be illegal under the Federal Food, Drug, and Cosmetic Act.” After subsequent meetings and discussions with the agency, including the submission of GRAS notification documents supporting the safety of the phytosterol ingredients (a step that would have been unnecessary if the products were marketed as dietary supplements), both products were marketed as functional foods. Similarly, FDA more recently issued an untitled or “courtesy” letter to a soup manufacturer notifying the company that its soups fortified with St. John’s wort and echinacea were not legally marketed as dietary supplements because “the clear implication of the label as a whole is to represent the Kitchen Prescription products as conventional foods.”

In terms of claims, functional foods, like conventional foods and dietary supplements, can make authorized health claims and nutrient content claims. Health claims are statements that characterize the relationship between a substance and a disease or health-related condition. Examples are calcium and osteoporosis, sodium and hypertension, and folate and neural tube defects. Foods bearing a health claim that is not authorized by regulation or under the recently promulgated notification procedure for health claims based on authoritative statements are considered misbranded and subject to regulatory action. As a legal matter, an unauthorized health claim or a claim that suggests that a food is intended to diagnose, treat, cure, or prevent disease subjects the product to regulation as a drug under section 201(g)(1) of the FD&C Act.

Nutrient content claims are statements characterizing the level of a nutrient in a food. Some examples of nutrient content claims are “high,” “more,” and “good source of.” As with health claims, nutrient content claims are authorized by regulation or through a notification procedure based on authoritative statements. A food bearing a nutrient content claim that has not been authorized by regulation or the notification procedure misbrands the product.

Similarly, FDA has acknowledged that conventional food/functional food can make the same breadth of structure/function claims as dietary supplements. Under DSHEA, structure/function claims (also known as “statements of nutritional support”) are defined as statements that:

1. Claim a benefit related to a classical nutrient deficiency disease and disclose the prevalence of the disease in the US (e.g., vitamin C and scurvy);
2. Describe the role of the nutrient or dietary ingredient intended to affect the structure or function in humans (e.g., increased intake of calcium decreases depletion of calcium from bones);
3. Characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function (e.g., studies in the Journal of the American Medical Association document that high levels of calcium aid the mineralization of bones); and
4. Describe the general well-being from consumption of a nutrient or dietary ingredient (e.g., taking vitamin C will help you feel healthy) (FD&C Act § 403(r)(6)(A).

Implicit and explicit claims to diagnose, treat, cure or prevent disease remain regulated as drug claims.

Notwithstanding these parallel labeling provisions, FDA has taken the position that conventional/functional food products can only make structure/function claims when the claimed effect is achieved through the “nutritive value” of the food. This interpretation, which places an additional burden on conventional/functional food manufacturers, has been very controversial, with many questioning FDA’s legal basis for such a distinction.

The term “nutritive value” has not been defined by FDA other then generally in its proposed and final rules on health claims where the agency stated that “nutritive value” is “value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy.” In public presentations and speeches over the past few years, FDA officials have acknowledged that the term is ill-defined and that the agency is struggling with it. However, in its January 30 letter to manufacturers, FDA stated: “as a legal matter, a structure/function claim on a food that is not achieved through nutritive value, or a claim that a food will treat or mitigate disease, subjects the product to regulation as a drug.
under section 201(g)(1) of the FD&C Act.”13 This unqualified public statement by FDA may portend greater vigilance and enforcement activity over structure/function claims made by conventional/functional food products.

In conclusion, it is clear that the functional food marketplace and demand are only going to grow. What is now a multi-billion dollar industry has enormous potential and opportunities under the current FDA regulatory framework. However, that being said, it is important for companies to recognize, as they develop their marketing plans, that terms such as “functional food” and “medical food” are not interchangeable and that conventional food products marketed for their health benefits, i.e., functional food, are subject to some FDA requirements that are distinct from dietary supplements, even though both may contain the same ingredients and bear the same claims.

NOTES:
1. Lofenalac, a product for persons with phenylketonuria (PKU) was the first FDA-recognized medical food and is still the prototypical medical food.
2. To obtain approval as a food additive, a petition must be submitted to FDA containing extensive scientific testing to demonstrate safety for the intended use. In contrast, an ingredient can be considered GRAS through an internal analysis or an FDA filing in the form of a notification. However, to support a GRAS determination, published literature must support the conclusion of qualified experts.
4. According to the FD&C Act, any substance intentionally added to food that is not GRAS or “prior sanctioned” is considered a “food additive.” The FD&C Act prohibits the marketing of a food additive unless FDA has published a regulation that approves the intended use of the substance. A food is “deemed to be adulterated” if it is, bears or contains an unapproved food additive. FD&C Act §§ 201(s), 409, and 402(a)(2)(C).
6. FDA Warning Letter from John B. Foret to Robert Ehrlich, Robert’s American Gourmet; January 27, 2000; see also FDA Warning Letter from John B. Foret to John Bello, South Beach Beverage Company; February 1, 2000.
11. 65 Federal Register 1000, 1050; January 6, 2000; (codified at 21 CFR § 101.93).

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