HUSCH BLACKWELL

The Future of Functional Foods

A Legal Guide to Product Development & Marketing

DECEMBER 2023

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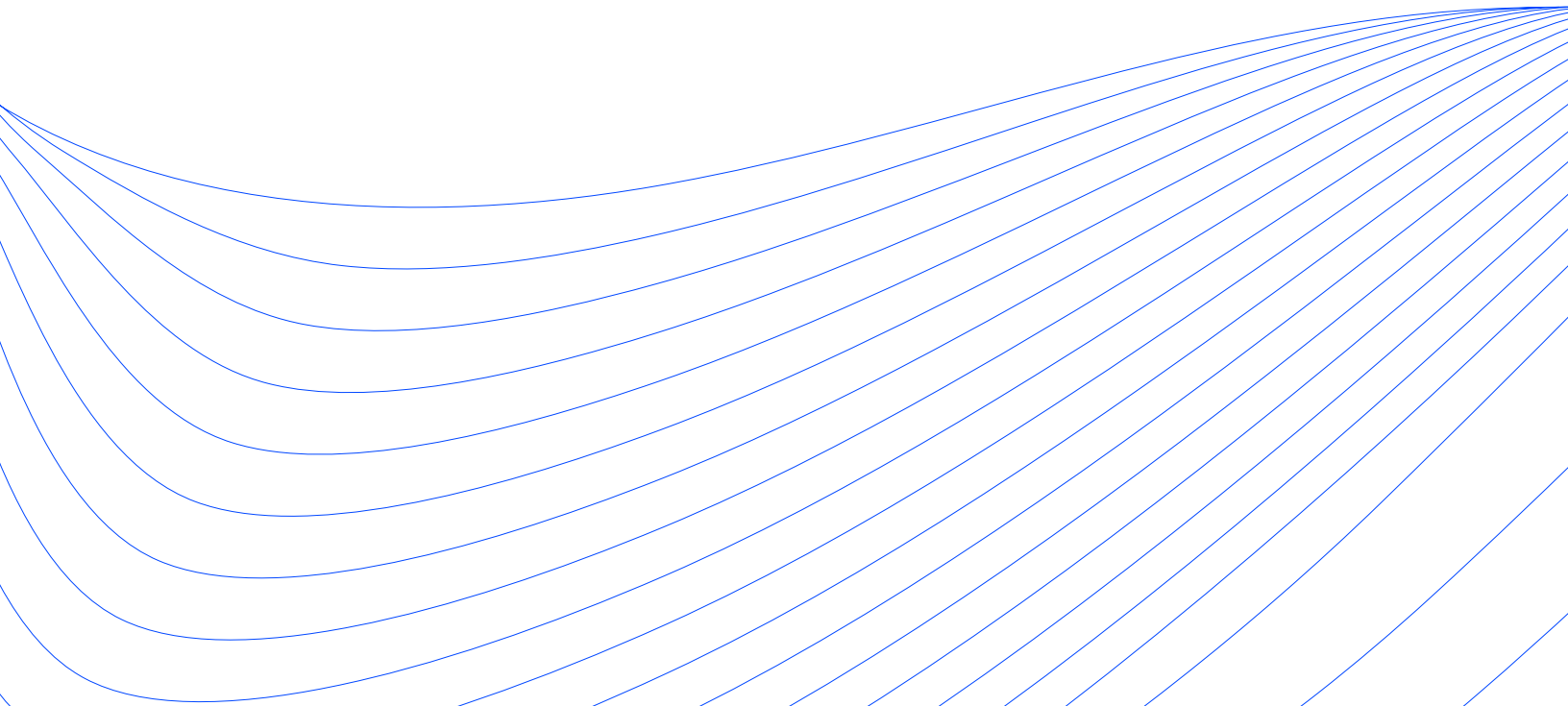


Introduction

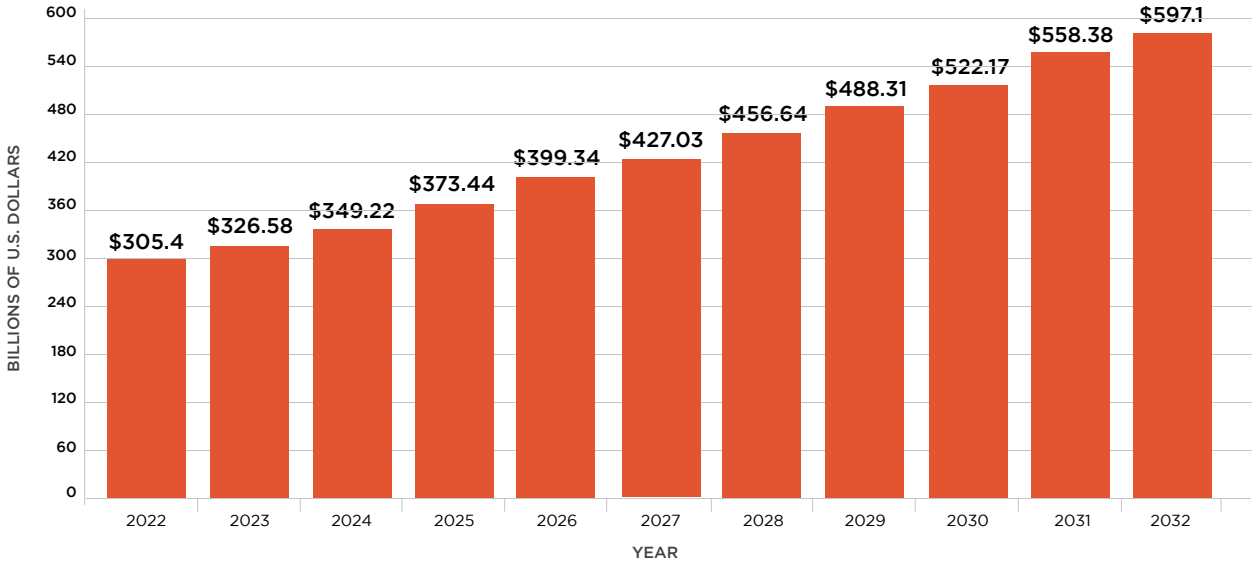
Following the social isolation and public health concerns associated with the COVID-19 pandemic, many Americans reevaluated their health and wellness priorities, creating new opportunities for food systems companies to connect with changing consumer tastes and preferences.

The newfound prevalence of functional foods—foods that purport to provide consumers with potential health benefits upon consumption—can be viewed as an expression of this prevailing consumer sentiment. In 2022, functional foods posted global revenues of approximately $305 billion, and the industry is projected to reach $597 billion by the end of 2032.

Consumers' increasing awareness of the advantages of nutrient-rich foods has prompted global food and beverage businesses to begin enhancing their products with nutritional additives. At the same time, innovators are introducing new products—and new product categories—into the market to target consumers' changing health and wellness needs.

Although most of these old (and new) products can be thought of as "functional" foods because of the purported health benefits, there is no legal definition for what constitutes a functional food in the United States. Instead, the Food and Drug Administration (FDA) places these functional foods into one of four categories: conventional foods, medical foods, dietary supplements, or drugs. While several bright-line rules make it relatively easy to avoid a product being categorized as a drug or medical food, the same cannot be said for conventional foods and dietary supplements. Product categorization is critical because conventional foods and dietary supplements are subject to different federal regulations.

FUNCTIONAL FOODS, PROJECTED MARKET GROWTH 2023-2032



Source: Precedence Research, May 2023, www.precedenceresearch.com/functional-food-market

The FDA is aware of the complexity associated with classifying a product as either a conventional food or dietary supplement, but has not provided straightforward guidance on the topic. Rather, the FDA conducts a holistic analysis of the product (including its labeling and marketing efforts) to determine its intended use and accompanying regulatory status. This creates a dilemma for functional food businesses looking to introduce new products into the market, as businesses need to determine whether their product is intended to be consumed as a conventional food or dietary supplement prior to production. A business must make its own determination of whether a product is a conventional food or dietary supplement prior to production, as the substances (i.e., ingredients) used may require FDA notification and/or pre-approval. Businesses use this self-determined classification as they further develop the product for market. However, this self-determined status can put businesses in a Catch-22 situation if the FDA disagrees with the categorization. This is because the FDA often does not review a product's categorization before it is marketed.

Much of a functional food product's commercialization cycle depends on the business's initial determination of whether their product is intended to be consumed as a conventional food or dietary supplement. As such, correctly categorizing a functional food is imperative prior to introducing the product to the market. In 2014, the FDA published a "guidance document" to assist businesses. While not legally enforceable, the guidance is an excellent summary of the factors at play in the FDA's holistic analysis of a product's intended use and provides areas for functional food businesses to consider before manufacturing their products and before introducing their products to market.

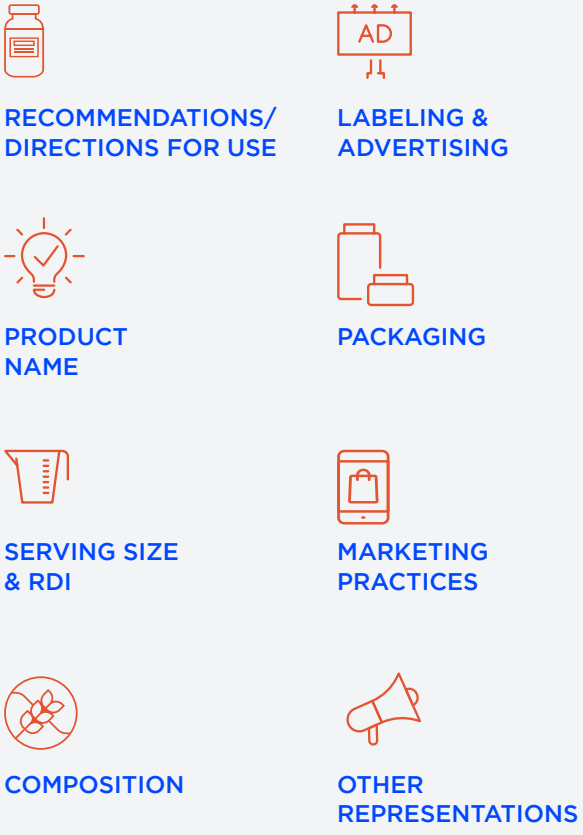
Recommendations and Directions for Use

Conventional foods are "consumed primarily for taste, aroma, and nutritive value," whereas dietary supplements are "intended to supplement the diet." Accordingly, this factor may be the most straightforward item for businesses to consider. For example, the FDA explained that a product's "intended use" will resemble an intended use for a conventional food if the product is intended to quench thirst, provide a source of fluids (toward the recommended 1.2 liters of daily intake), provide nutrition, or provide a taste or aroma. Conversely, the FDA clarified that products intended to supplement the diet in a manner consistent with other dietary supplements (e.g., take one tablespoon once a day) more closely resemble a dietary supplement.

Labeling and Advertising

The FDA will consider everything from the claims, statements, and graphics on the product's label, to how the product is advertised on the product's website and social media pages when evaluating the intended use of the product. The FDA used the following example to illuminate this point: A product may bear a Supplement Facts Panel and still be considered a conventional food if it bears a statement that the product is intended to "refresh" or "rehydrate" because this statement would represent the product for use as a beverage (which is categorized as a conventional food). In sum, the more a functional food is represented to perform a function traditionally reserved for conventional foods (such as rehydration, nutrition, or refreshment), the more likely the FDA will categorize the product as a conventional food.

FDA FACTORS USED IN CATEGORIZING FUNCTIONAL FOODS



Source: Food and Drug Administration, "Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages," January 2014.

Product Name

Although a simple consideration, the FDA takes into account a product's name when determining whether the product is represented for use as a conventional food or dietary supplement. Using standard terms for conventional foods (such as soda, drink, water, juice, tea, or cider) in the product name makes the FDA more likely to categorize the product as a conventional food.

Packaging

The FDA also considers the type of packaging used to hold and market the product, especially if the packaging conveys any messages about the product's intended use. The FDA will consider everything from the size, shape, color, design, volume, and serving size when considering a product's intended use based on its packaging. The more a product's packaging resembles that of a traditional conventional food product, the more likely the FDA will categorize the product as a conventional food. A common example from the FDA is that of a red, 12 oz pop-top aluminum can with silver script identifying the product as a "cola supplement" that is intended to be consumed in a single serving. In this example, the FDA would likely determine that the "cola supplement" better resembles a conventional food (like the well-known soda it resembles), regardless of the product name containing the word "supplement." Accordingly, if a business wants to market its functional food product as a dietary supplement, it should consider using packaging that does not resemble packaging commonly used for conventional foods.

Serving Size and Recommended Daily Intake

Conventional foods must include a Nutrition Facts Panel on their labels, which must identify the relevant "serving size" and declare the amount of calories, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrates, dietary fiber, total sugars, added sugars, protein, and certain vitamins and minerals.

Accordingly, the FDA will evaluate the serving size, Recommended Daily Intake (RDI), and Daily Recommended Value (DRV) to determine whether a product is being "consumed primarily for taste, aroma, and nutritive value" or if it is being used to "supplement" the diet. For instance, the FDA has reasoned that a liquid product that is "intended to be consumed in amounts that provide all or a significant part of the entire daily drinking fluid intake of an average person in the United States are effectively being represented as conventional foods."

Marketing Practices

The FDA considers the advertising and marketing practices used to promote a functional food product as part of its intended use analysis. The FDA has reasoned that, if a product is marketed as accompanying a meal or advertised for its taste, refreshment, or thirst-quenching capabilities, it resembles a conventional food; however, the FDA stated that a product is not always represented for use as a conventional food simply because it is marketed as a substitute for a beverage. A common example is that of an advertisement promoting a liquid vitamin C supplement as a "quick and easy alternative to drinking orange juice." In this case, the FDA reasoned that the product was intended to be used as a "more convenient source of vitamin C, not as a beverage to quench thirst, provide fluids, or wash down a meal." Additionally, businesses that want to categorize their functional food products as dietary supplements should avoid comparing their products to any conventional food (even in related search terms marketing) and placing their products next to conventional foods in retail stores.

Composition

A product's ingredients may be indicative of its intended use. Although the FDA recognizes that certain permitted ingredients may be used in both conventional foods and dietary supplements, the FDA primarily considers whether the product's composition, in combination with the factors discussed above, represents that the product is intended for use as a conventional food or dietary supplement. If a product is marketed as a dietary supplement but contains significant amounts of conventional food components unrelated to the claimed nutritional or health benefits of the dietary supplement, the FDA determine that the product is intended to be used as a conventional food, as opposed to a dietary supplement.

Other Representations

Businesses should ensure that any other representations made about their functional food product (whether on their social media pages or in publicly filed documents) align with the their intended use of the product, as the FDA considers all representations made about a product (whether on the product label or through the marketing and advertising of the product) in combination with each of the factors set forth above.

Product Categorization

The categorization of functional food products is the first and most important consideration in the preparation of new products for market; therefore, it is important that businesses be conversant with the legal definitions and concepts associated with the relevant categories.

There is no legal definition for functional foods in the United States. Instead, the FDA places these products into one of four categories—conventional foods, dietary supplements, medical foods, and drugs—each of which have different regulatory implications. Product categorization is critical because it determines whether a product must comply with the regulations set forth under the Federal Food, Drug, and Cosmetic Act (FDCA) and/or the Dietary Supplement Health and Education Act of 1994 (DSHEA).

Conventional Foods & Dietary Supplements

The FDCA definition of food includes both conventional foods and dietary supplements. In contrast, a drug is a substance *other than food* intended to affect the structure or any function of the body. These categories are all mutually exclusive. In other words, a functional food product cannot be dietary supplement if it is intended for use as a conventional food. Whether a product is intended for use as a conventional food or dietary supplement depends upon the product's various ingredients, along with how the product is represented for use (which such representations may be implied by the product name, stated on the product label, or even expressed as a health benefit). Notably, conventional foods themselves do not require FDA pre-market approval; however, any substance added to a conventional food is considered a "food additive" subject to FDA pre-market approval, unless:

- The substance is a previously approved food additive or color additive;
- The substance is generally recognized as safe (GRAS) for its intended use;
- The substance is a dietary ingredient or intended for use in a dietary supplement; or
- The substance falls under any other exemption to the food additive definition and, thereby, not deemed "adulterated."

> **"DIETARY SUPPLEMENTS"** are defined as "(1) a product (other than tobacco) intended to supplement the diet that bears or contains ... [a] dietary ingredient ... (2) means a product that ...(A) (i) is intended for ingestion ... (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and (C) is labeled as a dietary supplement...
>
> 21 U.S.C.A. §321(ff)

As alluded to earlier, the FDA regulates dietary supplements under the DSHEA, a different set of regulations than those covering conventional foods. In 1994, the DSHEA amended the FDCA (21 U.S.C.A. § 321(ff)) to include a three-part definition for dietary supplements (see inset above).

Contains a Dietary Ingredient

The FDCA defines a "dietary ingredient" to include vitamins and minerals; herbs and other botanicals; amino acids; "dietary substances" that are part of the food supply, such as enzymes and live microbials (commonly referred to as "probiotics"); and concentrates, metabolites, constituents,

extracts, or combinations of any dietary ingredient from the preceding categories. (21 U.S.C.A. § 321(ff)).

Not a Conventional Food

The FDA considers a variety of factors when determining whether a product is a conventional food. These factors include, among other things, the product's brand name, packaging, composition, serving size and recommended daily intake (i.e., volume of intended consumption), directions and recommendations for use, images or statements on the product's label, and how the product is advertised. Thus, it is important to keep in mind that a product's intended use determines its categorization, and the more each of these factors support its intended use, the more likely the product is to fall into a desired category.

Unlike functional foods, dietary supplements cannot be represented (i.e., intended for use) as a conventional food or as a sole item of a meal or the diet (e.g., as a "meal replacement"). A product may be intended for use as a conventional food if it is intended to provide taste and aroma, provide nutritional value, or quench thirst.

Although dietary supplements were historically found in forms such as pills, capsules, tablets, and powders, they are now taking the form of more prevalent conventional foods, such as protein bars, teas, and other beverages. Accordingly, it is imperative that businesses understand whether their product is represented as a conventional food prior to production and marketing.

Labeled as a Dietary Supplement

A product must also be labeled as a dietary supplement, meaning that the label must include the term "dietary supplement" or an equivalent (e.g., "iron supplement" or "herbal supplement"). Dietary supplements must also include a "Supplements Facts" panel, as opposed to a "Nutrition Facts" panel.

Medical Foods

A medical food is defined by the FDA in Section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)) as "a food which is formulated to be consumed or administered eternally 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, based on recognized scientific principles, are established by medical evaluation."

By definition and regulatory practice, the medical food category is something of a hybrid. Medical foods are not drugs and are not subject to drug regulations; however, they are required to be used under medical supervision.

Medical foods are distinct from functional foods (whether they are categorized as conventional foods or dietary supplements) because medical foods, among other things, must be formulated to meet distinctive nutritional requirements, must be used under medical supervision, and must be intended to the specific dietary management of a disease or condition.

Although medical foods provide consumers with health benefits upon consumption, they are distinct from other functional foods and therefore, like drugs, will not figure prominently in this guide.

DRUGS & FUNCTIONAL FOODS

Although less common, functional foods can also be categorized as a drug. The FDCA defines a "drug" in relevant part as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and … articles (other than food) intended to affect the structure or any function of the body of man or other animals …." (21 U.S.C.A. § 321(g)). Accordingly, functional foods companies should refrain from making any claims regarding a product's ability to "diagnose, cure, mitigate, treat, or prevent" diseases to avoid categorization of their product as a drug. Notably, any substance that has either undergone published clinical studies or been the subject of an Investigational New Drug (IND) application is precluded from use as a dietary supplement or a food additive, as it is inherently considered a drug.

Ingredients & Pre-Market Approvals

In conjunction with a product's category, a product's composition—its ingredients—is an important factor to consider and one that greatly impacts whether FDA notice or approval is required before bringing a product to market.

If a product is miscategorized and the appropriate regulations are not followed, the product may be deemed "adulterated" or "misbranded" and may be subject to seizure, penalties, fines, or even prosecution. Adulterated products cannot be imported or marketed in the United States. Under the FDCA, functional food companies are responsible for ensuring that their products are not adulterated.

Although there are several reasons why the FDA may deem a product adulterated, the most common pitfall for functional food companies to avoid is the use of ingredients that have not been recognized as safe for their intended use. Notably, the analysis of whether an ingredient is safe for its intended use depends on whether the ingredient is intended to be used as part of a conventional food, dietary supplement, drug, or medical food. This determination often turns on how a company represents its product in the marketplace.

Conventional Foods & Pre-Market Approvals

Conventional foods themselves do not require FDA pre-market approval; however, the ingredients added to conventional foods may require FDA pre-market approval. Generally, any substance (e.g., any functional food ingredient) that is reasonably expected to result—directly or indirectly—in it becoming a component or otherwise affecting the characteristics of any food is considered a food additive. All food additives require FDA pre-market approval, meaning that a petition must be filed with FDA (unless an exemption applies) in the form of a Food Additive Petition (FAP), which is a request to the FDA to issue a regulation allowing for the use of a new food additive. If the FAP is approved, the food additive (and its conditions for use) will be codified as law following the rulemaking process.

FUNCTIONAL FOODS & ADULTERATION

Generally, a functional food is adulterated if it bears or contains a poisonous or deleterious substance that makes it injurious to health, unless the substance is not an added substance. In other words, a functional food product may contain a naturally present deleterious—i.e. poisonous, toxic, or carcinogenic—substance so long as the intended use of the food will not result in an injury. Examples of poisonous naturally occurring substances include aflatoxins, which are produced by certain molds and grow in a variety of foodstuffs. A food may also be deemed adulterated if its bears or contains an unsafe food additive.

Additionally, under the DSHEA a dietary supplement may be deemed adulterated if (1) it presents a significant or unreasonable risk of injury or illness under the conditions of use set forth on the product label or, if appropriate conditions of use are not indicated on the product label, under usual conditions of use; (2) it poses an imminent hazard to public safety or health (as determined by the Department of Health and Human Services; or (3) it contains a New Dietary Ingredient, and there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.

Exemptions from Pre-Market Approval

A substance is exempt from the definition of a food additive—and thus from FDA pre-market approval—if it is generally recognized as safe by qualified experts under the conditions of its intended use in food or if it falls under another exception to the food additive definition in the FDCA (i.e., GRAS).

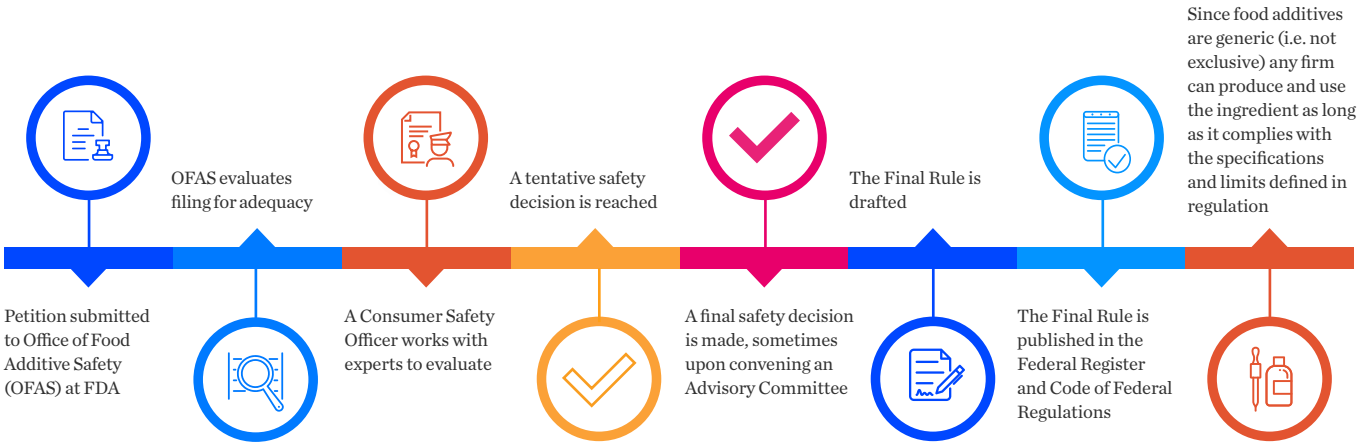
Generally Recognized as Safe (GRAS) substances are exempt from the definition of a food additive. A substance may be GRAS for its intended use through either its common use in food prior to 1958 or scientific procedures. To establish GRAS through common usage prior to 1958—a rare GRAS exemption—a company must present a substantial history of consumption of the substance for food prior to January 1, 1958. To establish GRAS through scientific procedures, there must be a consensus among qualified experts that the scientific data and information establish the substance is safe for its intended use.

Safe—in terms of GRAS—means that there is a reasonably certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use. Additionally, the scientific evidence used to establish the safety of the product must be generally available. Furthermore, there must be a basis for qualified experts to conclude the safety of the substance for its intended use.

Notably, a GRAS determination does not need to be submitted to FDA; however, the agency has a voluntary GRAS notification program through which a person can inform the FDA of a GRAS determination. Although the FDA has codified some GRAS ingredients, not all GRAS ingredients are codified in the FDCA.

If a food additive is not an approved food additive or GRAS, businesses may avoid the FDA pre-market approval process by utilizing one of the other food additive exceptions set forth in the FDCA. Some notable exemptions include (a) prior sanctioned substances that were authorized for use by FDA or USDA prior to 1958; (b) color additives and pesticides that comply with other pre-market approvals and established tolerances; and (c) dietary ingredients in or intended for use in a dietary supplement.

FDA FOOD ADDITIVE PETITION PROCESS



Source: Spoke Sciences, https://spokesciences.com/education/food-additive-petitions

Dietary Supplements

As noted above, dietary ingredients are not considered to be food additives and are, therefore, exempt from FDA pre-market approval when used in a dietary supplement. DSHEA, however, draws a distinction between "old dietary ingredients" (ODIs) and "new dietary ingredients" (NDIs) which impacts the pre-market notification process. To be considered an ODI, the dietary ingredient must have been marketed as a dietary ingredient, meaning that it was marketed in or as a dietary supplement, or for use in a dietary supplement, prior to October 15, 1994. An ingredient is not considered an ODI if the ingredient was used to make a conventional food prior to October 15, 1994.

Note that there is no authoritative list of ODIs; rather, functional food companies have the burden of providing evidence establishing that a dietary ingredient was, in fact, marketed for use as a dietary supplement before October 15, 1994.

Dietary ingredients marketed in the U.S. after October 15, 1994, are considered NDIs. Some NDIs may be marketed without FDA notification; others require pre-market notification. Businesses that use NDIs need to possess adequate information providing reasonable assurance that such NDI does not present a significant or unreasonable risk of illness or injury; otherwise, a dietary supplement containing an NDI is deemed adulterated.

NDIs & FDA Notification Requirements

NDIs that have been "present in the food supply as an article used for food in a form in which the food has not been chemically altered" may be immediately marketed without FDA notification or pre-market approval, provided they meet certain conditions (21 U.S.C.A. § 350b).

Even if FDA notification is not required, companies must have sufficient evidence to establish that the NDI will reasonably be expected to be safe.

If the NDI has not been "present in the food supply as an article used for food in a form in which the food has not been chemically altered," companies with products containing these NDIs must notify the FDA at least 75 days prior to marketing the dietary supplement containing the NDI. This 75-day pre-market safety notification must demonstrate that the NDI, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe.

The information provided to the FDA in this pre-market notification should include, at a minimum, citations to published articles that help form the basis that the NDI is reasonably expected to be safe for its intended use.

Unlike food additives, companies only need to have a basis for concluding that the NDI will reasonably be expected to be safe when used under the condition recommended or suggested on the dietary supplement's label, a much lower safety threshold.

The FDA generally responds to the pre-market safety notification and may:

- acknowledge the letter without objection;
- identify certain deficiencies in the notification;
- object to the marketing of the product due to safety concerns; or
- object for other regulatory issues with the NDI or Dietary Supplement.

The FDA does not have the authority to approve dietary supplements before they are marketed.

If the required pre-market safety notification is not submitted to the FDA, or if incomplete or inadequate information is provided, the Dietary Supplement containing the NDI is deemed to be "adulterated." Additionally, even if a pre-market safety notification is submitted as required, a dietary supplement containing an NDI will be considered "adulterated" unless there is a history of use or other evidence of safety establishing that the NDI, when used under the conditions recommended or suggested on the product label, will be reasonably expected to be safe.

The responsibility for ensuring the safety of dietary supplements (and the dietary ingredients contained therein) prior to marketing rests solely with functional food companies. The FDA's role in the regulation of dietary supplements increases after the product reaches the market—at which point the FDA takes action against adulterated or misbranded dietary supplements.

Labeling Requirements

As with so much else in the product development lifecycle, safety and labeling requirements depend on proper product categorization.

A product's intended use has a significant bearing on its classification, and one of the most important factors the FDA considers when categorizing a product is how the functional food company classifies the product on its label.

Accordingly, many functional foods may be unintentionally misbranded because their labels (or other representations, such as advertisements) are inconsistent with the product category under which they are being marketed. In other words, a product may be branded and marketed as a dietary supplement, but its label may represent the intended use of the product as a conventional food, which would require that the product follow different safety and labeling requirements.

All functional foods—including conventional foods and dietary supplements—are subject to the labeling requirements of the Nutrition Labeling and Education Act of 1990 (NLEA); furthermore, all functional foods, regardless of their categorization, contain a Principal Display Panel (PDP) and an Information Panel. The PDP is the front label, printed on the side most likely to be displayed to a customer for sale. The panel adjacent to and to the right of the PDP is the Information Panel. Additionally, the FDCA requires that all labeling (including any claims made on a product's label) be truthful and not misleading. Notably, some dietary supplements may be exempt from certain nutrition labeling requirements if the product does not contain any claims or nutrition information.

Principal Display Panels & Information Panels

The PDP for both conventional foods and dietary supplements must include the Statement of Identity (SOI) and Net Contents. SOI is the name of the conventional food or dietary supplement. A Standard of Identity, which is codified in regulation, helps to ensure consistency in characteristics and consumer expectations. If there is no established Standard of Identity, the common or usual name of the food can be used (e.g., "cookies"). If there is no common or usual name, then a descriptive name must be used. The Net Contents is simply the amount of food or dietary supplement contained in the package (e.g., NET WT 3.8oz (180g)).

PRINCIPAL DISPLAY PANEL & INFORMATION PANEL: AN EXAMPLE

A product's categorization as a conventional food or dietary supplement has a more drastic impact on the contents of the product's Information Panel. For example, the Information Panel for conventional foods includes a Nutrition Facts Panel, whereas the Information Panel for dietary supplements contains a Supplement Facts Panel. Notably, the PDP on dietary supplements must identify the product as a dietary supplement, or equivalent term replacing "dietary," with the name or type of dietary ingredient in the product (e.g., "iron supplement" or "herbal supplement") and must include all necessary FDA disclosures.

Conventional Food Information Panels

The Information Panel for conventional foods is familiar to most consumers as the place where nutrition facts are found as part of a Nutrition Facts Panel. The Information Panel for conventional foods must also contain the ingredient list; the signature line (the name and address of the manufacturer, packer, or distributor responsible); and any required allergen disclosures and USDA bioengineered labeling. Notably, dietary ingredients cannot be listed in the Nutrition Facts Panel.

The Nutrition Facts must include a "serving size" and refer to the RDI and DRV, when applicable, for calories, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, dietary fiber, total sugars, added sugars, protein, and certain vitamins and minerals.

Dietary Supplements Information Panels

The Information Panel for dietary supplements is nearly identical to the Information Panel on conventional foods (with the inclusion of allergens and signature line), but there are a few key differences. The Supplement Facts Panel includes information regarding all dietary ingredients regardless of whether a RDI or DRV is established; conventional foods are only required to include specific nutrients. The Supplement Facts panel must also list the serving size and number of servings per container, declare each dietary ingredient in the product, and provide information on the amount of the dietary ingredient per serving (except for dietary ingredients that are part of a proprietary blend, which ingredients can be grouped together).

Additionally, unlike conventional foods (which cannot list dietary ingredients in the Nutrition Facts Panel), dietary supplements must identify the dietary ingredients in the Supplement Facts Panel. Additionally, the source of the ingredients may also be listed in the Supplement Facts Panel (e.g., "calcium (as calcium carbonate)").

Another notable difference between the Nutrition Facts Panel (for conventional foods) and the Supplement Facts Panel (for dietary supplements) is that the "signature line" for dietary supplements must list a domestic address or domestic phone number for reporting serious adverse events.

As with the Nutrition Facts Panels for conventional foods, dietary supplements' Supplement Facts Panels must list major allergens.

Nutrition Facts

8 servings per container
Serving size **2/3 cup (55g)**

Amount per serving
Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 240mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Source: U.S. Food and Drug Administration, "The New Nutrition Facts Label: Examples of Different Label Formats."

Supplement Facts

Serving Size 1 Packet
Serving Per Container 10

Amount Per Packet		% Daily Value
Vitamin A (from cod liver oil)	900 mcg	100%
Vitamin C (as ascorbic acid)	250 mcg	278%
Vitamin D (as ergocalciferol)	20 mcg	100%
Vitamin E (as dl-alpha tocopherol)	75 mcg	500%
Thiamin (as thiamin mononitrate)	60 mcg	5000%
Riboflavin	60 mcg	4615%
Niacin (as niacinamide)	60 mcg	375%
Vitamin B_6 (as pyridoxine hydrochloride)	60 mcg	3529%
Folate	400 mcg DFE (240 mcg folic acid)	100%
Vitamin B_{12} (as cyanocobalamin)	100 mcg	4167%
Biotin	100 mcg	333%
Pantothenic Acid (as calcium pantothenate)	60 mcg	1200%
Choline (as choline chloride)	100 mcg	18%
Calcium (from oystershell)	130 mcg	10%
Iron (as ferrous fumarate)	10 mcg	56%
Iodine (from kelp)	150 mcg	100%

Amount Per Packet		% Daily Value
Magnesium(as magnesium oxide)	63 mcg	15%
Zinc (as zinc oxide)	11 mcg	100%
Selenium (as sodium selenate)	25 mcg	45%
Copper (as cupric oxide)	0.5 mcg	56%
Manganese (as manganese sulfate)	5 mcg	217%
Chromium (as chromium chloride)	50 mcg	143%
Molybdenum (as sodium molybdate)	50 mcg	111%
Potassium (as potassium chloride)	200 mcg	4%
Betaine (as betaine hydrochloride)	25 mcg	*
Glutamic Acid (as L-glutamic acid)	25 mcg	*
Inositol (as inositol monophosphate)	75 mcg	*
para-Aminobenzoic acid	30 mcg	*
Deoxyribonucleic acid	50 mcg	*
Boron	500 mcg	*

*Daily Value not established.

Other ingrediets: Cellulose, stearic acid, and silica.

Source: *Code of Federal Regulations*

Additional Labeling Considerations

Aside from the technical labeling requirements discussed above, another critical aspect of correctly categorizing a functional food product as either a conventional food or dietary supplement is the type of statements, graphics, and "claims" that can be made on a product's label. As previously discussed, the FDA considers a variety of factors when determining whether a product is intended for use as a conventional food or dietary supplement. Such factors include the statements and graphics placed on a product's label, as these items may unintentionally misbrand the product.

The FDA considers statements made on a product's label when evaluating the intended use of a product. For example, "a product that bears a Supplement Facts Panel may still be a conventional food if it also bears statements that the product is intended to 'refresh' or 'rehydrate' because such statements represent the product for use as a beverage, i.e., a conventional food."

Note that all claims, statements, and graphics on a product label are subject to 21 U.S.C.A. § 343, which provides that a food is misbranded if its labeling is false or misleading.

KEY LABELING TAKEAWAYS

- ☑ The intended use of a functional food product is a holistic analysis, and the technical requirements of a product's label are not determinative of a product's categorization.
- ☑ The use of any graphics (e.g., symbols, vignettes, pictorial serving suggestions) depicting a product as having an intended use resembling that of the contrary regulatory category could invite unwanted regulatory scrutiny. For example, the FDA has found that "an ad or label with a picture of a liquid product being poured onto a green salad would represent the product as a salad dressing."
- ☑ Any statements and/or graphics included on a product's label and/or packaging should align with the intended use and desired categorization of their product.

Source: Code of Federal Regulations

Product Claims

A product's categorization impacts the claims that can be made about the product—whether on the product label or as part of the product's marketing.

In the functional food industry, both conventional foods and dietary supplements often contain ingredients that may reduce the risk of a health condition or impact the structure or function of the human body; however, the types of claims that can be made about a functional food product depend on whether the product is categorized as a conventional food or dietary supplement. There are three categories of claims defined by FDCA and FDA regulations: health claims, nutrient content claims, and structure/function claims.

Health Claims

A health claim is an explicit or implied characterization of the relationship between (a) a substance and (b) a disease or a health-related condition (e.g., "Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors"). A health claim does not exist if no assertion is made about the reduced risk of a disease or health condition (e.g., "fruits and vegetables are good for your health"). Functional foods may make health claims by way of a written statement, third-party reference, symbol, or vignette on their product label but cannot include any claims about the diagnosis, cure, mitigation, or treatment of diseases, as such claims would categorize the product as a drug under the FDCA. All health claims must be reviewed and approved by the FDA prior to their use on a product.

There are two types of health claims: (1) authorized health claims and (2) qualified health claims. Authorized health claims are claims that have been reviewed by the FDA and authorized for use on food products or dietary supplements to show that consumption of a functional food product may reduce the risk of a disease or a health-related condition. Authorized health claims require "significant scientific agreement" among qualified experts that the claim is supported by the totality of publicly available scientific evidence for a substance/disease relationship.

New health claims may be "authorized" by submitting a notification to the FDA of a claim based on an "Authoritative Statement" from certain scientific bodies of the U.S. government, such as the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), or the National Academy of Sciences. Note that these "Authoritative Statements" cannot be used to support health claims for dietary supplements.

Qualified health claims are claims supported by scientific evidence that do not meet the "significant scientific agreement" standard necessary for authorized health claims. They often arise from emerging evidence regarding a relationship between a food substance and a reduced risk of a disease or health-related condition (e.g., "Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer"). In these cases, petitioners may submit a request to the FDA asking that it review the available scientific evidence and exercise discretion to permit the use of the requested health claim. If the FDA finds that the evidence supporting the proposed health claim is supported by credible scientific evidence and that the claim can be "qualified" so as to prevent it from misleading consumers, the FDA will issue a letter to the petitioner with specific guidelines about how the claim can be made.

To ensure that these claims are not misleading, the FDA requires the use of a disclaimer (or other qualifying language) to ensure that consumers are not misled. The strength of these disclaimers will vary depending on the amount of scientific evidence present to support the health claim. Notably, qualified health claims can be used on any conventional food or dietary supplement product so long as the claim is used in compliance with the parameters set forth in the FDA's response letter.

Nutrient Content Claims

Both conventional foods and dietary supplements may also bear nutrient content claims, or claims that characterize the level of a nutrient or dietary substance in a product outside of the Information Panel. Nutrient content claims may be express or implied and must be authorized by the FDA and made in accordance with FDA regulations. Nutrient content claims describe the level of a nutrient in the product, using terms such as "free" "high-in," "low-in," or "a good source of," or they may compare the level of a nutrient in a food to that of another food, using terms such as "more," "reduced," or "lite."

Businesses can only use the claims—or their synonyms—specifically defined in the FDA's regulations. Nutrient content claims must also meet specified FDA criteria. In other words, businesses can only make these claims if their products meet the nutrient thresholds defined by law. For example, a product can only include the terms "high," "rich-in," or "excellent source of" if the food contains 20% or more of the RDI or the DRV per customary serving size. Nutrient content claims also include antioxidant claims, high-potency claims, and claims.

Note that accurate quantitative statements that do not characterize the nutrient level of a product (e.g., 100 mg of cholesterol) are not considered nutrient content claims; however, the phrasing of such a statement is important, as claiming that a product has "only 100 mg cholesterol" implies a "low" level of cholesterol, and, thereby, would be considered a nutrient content claim. Also, nutrient content claims require the use of a disclosure statement if the product includes more than a specified level of fat, saturated fat, cholesterol or sodium.

Structure/Function Claims

Both conventional foods and dietary supplements can bear structure/function claims. Structure/function claims are claims that describe the role of a nutrient or dietary ingredient in maintaining the normal structure (e.g., skeletal system) or function (e.g., urinary tract) of the human body. For example, a traditional structure/function claim may provide that "fiber maintains bowel regularity," or "antioxidants maintain cell integrity." Unlike health claims, structure/function claims do not make reference to a disease or health-related condition.

Notably, conventional foods' structure/function claims must be tied to a specific nutrient. In contrast, dietary supplements can make broad structure/function claims about the entire product (without focusing on nutritive value). In short, a conventional food can bear any structure/function claim so long as the claim is tied to a nutrient in the food (not an ingredient in the food).

Although manufacturers of conventional foods and dietary supplements do not need to obtain FDA pre-market approval for structure/function claims, they must have substantiation that the structure/function claim is truthful and not misleading. Notably, anyone who makes structure/function claims about a dietary supplement must notify the FDA no later than 30 days after marketing the dietary supplement. In contrast, conventional food businesses do not need to notify the FDA about any structure/function claims.

Additionally, dietary supplements containing any structure/function claims must include an FDA warning, which must read, "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." This FDA disclaimer is not needed on conventional food labels.

In sum, although the types of claims that can be made about a functional food product depend on whether the product is categorized as a conventional food or dietary supplement, all claims must be truthful and cannot be false or misleading, as all claims, statements, and graphics on a product label are subject to 21 U.S.C.A. § 343, which provides that a food is misbranded if its labeling is false or misleading. Businesses must comply with all the requisite FDA regulations regarding the use of any health, nutrient content, or structure/function claims. If a business fails to comply with these regulations, the FDA would consider that the product is either misbranded (mislabeled and therefore illegal) or, worse, an illegal drug because it would not comply with all applicable drug requirements.

PARSING THE SEMANTICS OF PRODUCT CLAIMS

PERMISSIBLE STRUCTURE FUNCTION CLAIM	DISEASE CLAIM
"Helps promote digestion"	"Heals stomach or duodent lesions"
"Improves mild memory problems associated with aging"	"Prevents the onset of Alzheimer's"
"Maintains healthy lung function"	"Maintains healthy lungs in smokers" or "Promotes a tumor-free state"
"Supportive of mood swings or hot flashes in menopausal women"	"Helps ease depression during menopause"
"Curbs appetite to help with weight loss"	"Diuretic" or "obesity treatment"

Source: Mundel, Benjamin and Jacquelyn Fradette, "Take these 3 steps to substantiate your dietary supplements' claims".

Advertising

The need for functional food companies to be truthful in representing their products extends from the label to all advertising and marketing efforts.

The FDA is responsible for ensuring the safety and labeling of products. Specifically, 21 U.S.C.A. § 343 prohibits "labeling [that] is false or misleading in any particular [aspect]." In contrast, the Federal Trade Commission (FTC) is generally responsible for the advertising of such products once they are introduced into interstate commerce, as Section 5 of the Federal Trade Commission Act prohibits "unfair or deceptive acts or practices," and "any false advertisement" that is "misleading in a material respect." The FTC is primarily tasked with ensuring that advertisements are truthful and not deceptive or misleading and that all claims are substantiated. The two agencies often work closely together when the subject of an FTC inquiry is an entity regulated by the FDA.

Deceptive Advertisements

The term "advertising" refers not only to traditional TV, radio, print, and internet ads, but also to any marketing techniques and promotion methods used to increase consumer interest or demand for their products. Advertising includes statements or depictions on packaging and labeling, promotional materials such as brochures or booklets, social media and influencer marketing, and many other intermediaries. A deceptive advertisement is one that contains a material misrepresentation or omission that is likely to mislead consumers acting reasonably under the circumstances.

To determine whether an advertisement is deceptive, the FTC (1) identifies the representations made by an advertisement, (2) considers the representations from the perspective of a reasonable consumer, and (3) determines whether the representation is material.

As discussed earlier, businesses may make certain representations about the intended use of the products by the type of statements, graphics and claims used on a product's label or as part of the product's advertising. Such representations can be express or implied. Express claims make a direct representation (e.g., this is a "dietary supplement"). Implied claims require the FTC to examine the net impression of an advertisement, including the juxtaposition of any statements, images, and claims.

Conversely, just as an advertisement can be deceptive by way of its express or implied representations, an advertisement also can be deceptive because of what it fails to say. Under Section 5 of the FTC Act, if an advertisement would be misleading without certain key qualifying information, that information must be clearly and conspicuously disclosed. The FTC will consider the totality of the circumstances when determining whether a consumer, acting reasonably under the circumstances, would be deceived by the representation, or omission, used in the advertisement. Because the FTC uses the "reasonable customer" standard, the advertiser's intent is irrelevant.

Lastly, to determine whether an advertisement is deceptive, the FTC will consider whether the representation was "material", in that it is likely to affect a consumer's choice or conduct regarding a product.

Substantiated Claims

In addition to ensuring that advertisements are not deceptive, businesses need to confirm that any claims being made are substantiated. The FTC Act requires advertisers to have a reasonable basis for their product claims before disseminating an advertisement. For example, dietary supplements cannot utilize structure/function claims to market or advertise unless at the time the claim is made, the advertiser possesses and relies upon a reasonable basis substantiating the claim. As a general rule, the FDA applies a substantiation standard of "competent and reliable scientific evidence" when evaluating claims about the benefits and safety of foods, drugs, and dietary supplements. Functional food companies should consult and be familiar with the FTC's Health Claims Guidance, which was published in December 2022.

Advertising & Imputed Liability

Businesses need to be aware of the FTC's advertising regulations and relay these principles to their agents, as liability for deceptive and unsubstantiated claims is imputed to anyone who has the authority to control the marketing of a product (whether directly or indirectly). In recent years, the FTC has taken action against parties ranging from individual owners and corporate officers to product marketers, distributors, ad agencies, and endorsers.

Accordingly, companies should ensure that their marketing and advertising practices (including any statements, graphics, or claims used on the product label or as part of the product's marketing strategy) align with the intended use, and desired categorization of, their product. Additionally, companies need to ensure that any endorsers disclose their relationship to the business and refrain from providing false or misleading statements regarding the product.

Note that "disease claims" (i.e., claims regarding the diagnosis, cure, mitigation, or treatment of diseases that are used on a Conventional Food or Dietary Supplement) are one of the most common types of advertising claims challenged by the FTC.

AN ADVERTISING CHECKLIST FOR FUNCTIONAL FOODS

- ☑ "Disease claims" (i.e., claims regarding the diagnosis, cure, mitigation, or treatment of diseases that are used on a conventional food or dietary supplement) are one of the most common types of advertising claims challenged by the FTC.
- ☑ Carefully consult FTC guidance on the use of testimonials and endorsements. Although the Enforcement Guides do not have the force of law, they provide insight into how the FTC views certain marketing activities. Principally, when marketing their products, companies need to ensure that any endorsers disclose their relationship and do not provide false or misleading statements regarding the product.
- ☑ Even ingredients that have a long history of use must still satisfy the "substantiation requirement," i.e., the marketer must be able to provide "competent and reliable scientific evidence" to support any claims made about the product.
- ☑ While outside of the scope of the FTC Act, DSHEA mandates that advertisers of a dietary supplement using a structure/function claim must include an FDA disclaimer providing that (1) the statement has not been evaluated by the FDA and (2) the product is not intended to diagnose, treat, cure, or prevent any disease. However, such a disclaimer does not remediate an otherwise "deceptive" advertisement.
- ☑ Advertisers need to take caution not to overstate any FDA assessments or scientific evidence to support a product claim, such as a failure to comply with FDA-issued guidelines. Never assume that the FDA has approved a claim on any other basis other than the one explicitly issued.
- ☑ Businesses that utilize third-party literature (i.e., books, newspaper articles, or scientific abstracts) to market their products need to ensure that these materials are not deceiving to consumers. Liability may be imputed to advertisers who, through the use of such third-party literature, make certain claims about their products. Refer to 21 U.S.C.A. § 343-2 for a full treatment of the exception from labeling requirements for certain scientific journal articles, books, and other publications used in the sale of dietary supplements.

Regulatory Enforcement

Both adulterated and misbranded products are subject to federal enforcement, and such enforcement could serve as a springboard for private litigation, amplifying the risks associated with developing and bringing functional foods to market.

If a product is misclassified at the beginning of the product development lifecycle, there is a high likelihood that appropriate safety and labeling requirements were not followed, thus increasing the risk that a product is adulterated or misbranded. Adulterated and/or misbranded foods cannot be legally imported or marketed in the United States.

The FDA and the FTC share jurisdiction over deceptive or misleading claims made by functional food companies, and both regulatory agencies may take action against functional food companies that who sell misbranded products.

Regulatory Enforcement Tools

The primary enforcement concerns for functional food businesses engaged in the sale of allegedly adulterated and/or misbranded products include FDA Warning Letters, product recalls, and FTC Warning Letters and enforcement actions.

FDA Warning Letters

The most public consequence of making an impermissible claim for a functional food company is becoming the subject of an FDA Warning Letter, which are frequently issued to those who have violated FDA regulations. These publicly available Warning Letters not only identify the alleged legal violations but also provide a detailed description of the violation. Warning Letters will also provide directions for the company to inform the FDA of its plan to correct the violation.

Product Recalls

In addition to issuing Warning Letters, the FDA also has authority to force the removal of a food from the market if the food violates FDA regulations. Recalls are categorized into classes depending on the severity of the violation. Although recalls may be conducted by a business's own initiative, recalls can be mandated when the FDA determines that a product is unsafe or adulterated and needs to be immediately removed from the market. Recalls may also be used if misbranded products, or products containing allergens, need to be removed from the market. Additionally, the FDA may mandate a recall if a company refused to conduct a recall, does not timely remove product from the market, or fails to take prompt corrective action and continues to introduce product into the market.

In addition to product recalls, businesses that violate FDA regulations may be subject to orders from judges preventing the company from selling its products (i.e., injunctions), seizures of products, penalties, fines, or even prosecution without further notice.

Similar to FDA Warning Letters, most recalls and market withdrawals are publicly available and may be used as a foundation for private litigation and/or industry self-regulatory activities.

FTC Warning Letters and Enforcement Actions

Similar to the FDA (which focuses on safety and labeling matters), the FTC issues public Warning Letters to businesses that have violated the FTC Act. In addition to issuing Warning Letters, the FTC also has the authority to bring federal lawsuits for violations of the FTC Act and to bring civil penalties or fines against violators.

Industry Self-Regulation & Private Litigation

Given that government enforcement actions are often publicly available, competitor businesses may use these actions as the foundation for a review by the National Advertising Division (NAD). An independent nonprofit organization that evaluates the truth and accuracy of national advertising, NAD reviews challenges to advertising brought by consumers, businesses, trade associations, or even the NAD itself. While FDA Warning Letters and/or product recalls do not always lead directly to FTC enforcement, any publicly available information may be used by advertisers who would like to sue their competitors and force the removal of a competitive product from the market.

Similar to the risks associated with NAD actions, there is a high likelihood that plaintiff's attorneys will use publicly available enforcement information as the foundation for private actions against prominent functional food businesses (particularly those with the financial resources to pay large settlements and legal judgments). Accordingly, even if a business remediates an alleged violation set forth in a Warning Letter and avoids further enforcement from the FDA, the business may be an easy target for plaintiffs seeking civil damages arising from such allegations.

Private civil actions, brought as false advertising cases, are generally brought under state consumer protection and unfair trade practice laws. Private civil actions cannot be brought under the FDCA or FTC Act, as these statutes do not include a private right of action. However, violations of the FDCA and FTC Act have served as the basis for private litigation. Businesses who sell adulterated products are often sued under a personal injury claim if the individual is injured by the product.

> "Functional food businesses need to take caution to avoid violating federal and state law, as plaintiff's attorneys continue to benefit from filing lawsuits alleging that individuals have either been harmed by an adulterated product or misled by a product's label or advertising.

About Us

While there is no exact science to selecting the proper categorization for your functional food product, Husch Blackwell can help your business determine the best regulatory pathway to market your product and ensure that it complies with all FDA requirements.

Given the myriad of options for businesses looking to participate in the functional food industry, the one clear takeaway is that a savvy producer will want a dedicated and experienced team to assist while navigating this complex regulatory process.

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