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Understanding Functional Food Categories and Their Implications

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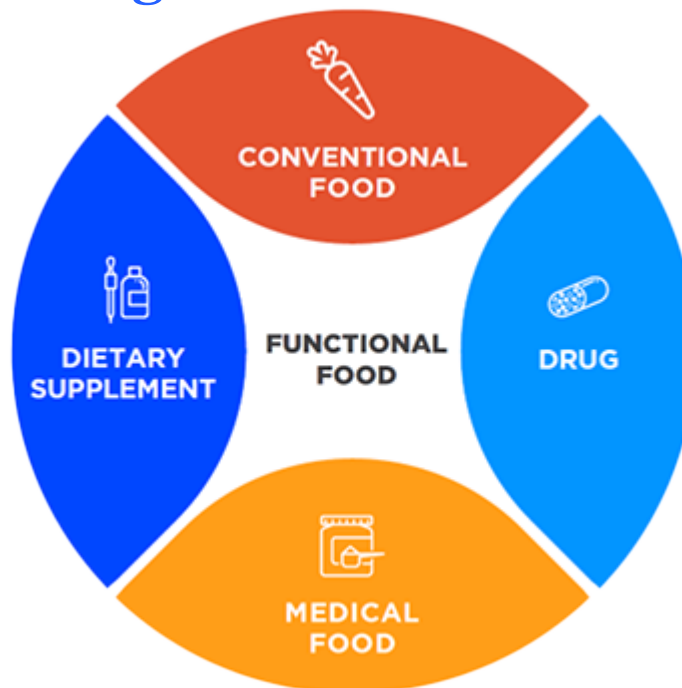
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There is no legal definition of what constitutes a “functional food” or a “functional beverage.” Rather, the Food and Drug Administration (FDA) places functional foods and functional beverages into one of four categories—conventional foods (including beverages), dietary supplements, drugs, and medical foods—each of which have significantly different regulatory implications on the production and

marketing of a product.

Despite limited FDA guidance on the matter, companies are left to make their own determination of whether a product is intended to be consumed as a conventional food or dietary supplement prior to production.

Correct product categorization is critical, as 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.

The Federal Food, Drug, and Cosmetic Act (FDCA) defines “food” 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.” The FDCA’s definition of food includes both conventional foods and dietary supplements.

What Is a conventional food?

Conventional foods are foods “consumed primarily for taste, aroma, and nutritive value.” Beverages are commonly considered a subcategory of conventional foods under the FDCA.

Whether a product is intended for use as a conventional food depends, among other things, on the product’s ingredients and how the product is represented for use (which may be inferred by a variety of factors, including the product name, the product label, and even the product’s purported health benefits).

What is a dietary supplement?

Unlike conventional foods, dietary supplements are not consumed primarily for their taste or aroma and cannot be represented for use as a sole item of a meal or diet.

The Dietary Supplement Health and Education Act of 1994 (DSHEA) defines dietary supplements 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...” Dietary supplements cannot be represented for use as a conventional food and must contain a dietary ingredient.

Dietary ingredients include:

vitamins (e.g., multivitamins or individual vitamins such as vitamin D and biotin)

minerals (e.g., calcium, magnesium, and iron).

herbs and other botanicals (e.g., echinacea and ginger)

botanical compounds (e.g., caffeine and curcumin)

amino acids (e.g., tryptophan and glutamine)

dietary substances, such as enzymes and live microbials (often referred to as probiotics)

concentrates, metabolites, constituents, extracts, or combinations of any of the foregoing categories

Although dietary supplements were historically manufactured 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, coffees, sport drinks, juices, and meal replacement shakes.

How does the FDA determine whether a product is a conventional food or dietary supplement?

The FDA conducts a holistic analysis of the product (including its labeling and marketing efforts) to determine its intended use and accompanying regulatory status.

The FDA's intended use analysis is informed by a variety of factors (see graphic). Because the FDA regulates dietary supplements under a different set of regulations than those covering conventional foods (i.e., DSHEA vs. FDCA), the FDA's post-market classification of your functional food product will retroactively determine whether you complied with the appropriate regulations when manufacturing and marketing your product.

If the FDA determines that your product is miscategorized, and the appropriate regulations were not followed, your product may be deemed unsafe (i.e., adulterated) or misbranded (due to any false or misleading advertisements), which could lead to your product being recalled or, worse, your business being subject to FDA enforcement or private liability.

Our team has made available a guide—*The Future of Functional Foods*—that further explains how the FDA may categorize a functional food product. While there is no exact science to selecting the proper category for a functional food product, Husch Blackwell can help businesses navigate the complex regulatory scheme and determine the best avenue to ensure that a functional food product complies with all FDA requirements.

FDA FACTORS USED IN CATEGORIZING FUNCTIONAL FOODS



RECOMMENDATIONS/
DIRECTIONS FOR USE



LABELING &
ADVERTISING



PRODUCT
NAME



PACKAGING



SERVING SIZE
& RDI



MARKETING
PRACTICES



COMPOSITION



OTHER
REPRESENTATIONS

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