US Food and Drug Administration Regulations Governing Label Claims for Food Products, Including Probiotics

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The US Congress has granted the Food and Drug Administration the authority to permit manufacturers to use claims in food labels that fit into the following broad categories: health claims, structure/function claims, nutrient content claims, and dietary guidance messages. This article outlines the scope and evolution of these claims and how they are used in the marketing of probiotics. Probiotics are live microorganisms (in most cases, bacteria) that are similar to beneficial microorganisms found in the human gut.

The Nutrition Labeling and Education Act of 1990 gives the US Food and Drug Administration (FDA) the authority to regulate health claims on food labels [1]. These claims describe the link between specific nutrients or substances in food and a particular disease or health-related condition [2]. The Nutrition Labeling and Education Act permits health claims if there is evidence to support the claim, there is significant scientific agreement among qualified experts about the claim, and the claim is not misleading. A claim is permitted if the substance that is the subject of the health claim contributes “taste, aroma, or nutritive value, or any other technical effect…to the food” [3].

The FDA Modernization Act of 1997 permits manufacturers to use health claims based on authoritative statements by a scientific body of the US government, such as the National Institutes of Health [4]. The FDA Modernization Act gives the FDA the right to prohibit or modify, on the basis of relevant regulations, a health claim 120 days after receipt of notification from a manufacturer requesting use of such a claim.

The significant scientific agreement standard of the Nutrition Labeling and Education Act was overturned by court decisions in 1999 and 2002, which ruled on the basis of the First Amendment that the standard was overly restrictive. The court ruled in favor of the defendants by stating that health claims that did not meet the significant scientific agreement standard should be permitted, as long as the statements were truthful and not misleading when appropriately qualified to indicate the level of scientific support for the claim [5]. These types of claims are now referred to as “qualified health claims,” whereas claims that satisfy the significant scientific agreement standard of the Nutrition Labeling and Education Act are referred to as “unqualified health claims.” As part of the 2003 Consumer Health Information for Better Nutrition Initiative, the FDA announced a framework for regulating qualified health claims [5]. Under this framework, the FDA issues a letter of enforcement discretion for qualified health claims. Although the “enforcement discretion” letter is issued to the petitioner who requested the qualified health claim, the claim can be used by other marketers on products that meet the criteria for the claim that are specified in the letter [6]. For example, the qualified health claim of an association between omega-3 fatty acids and a reduced risk of coronary heart disease is currently widely used in the marketing of omega-3 products.

The FDA published a document that outlines the process by which it systematically reviews the scientific literature to determine the level of scientific agreement in support of a claim [2]. Health claims are authorized...
by the agency only after a systematic review of scientific evidence [5]. The process involves the following steps: define the substance-disease relationship that is the subject of the claim, identify relevant studies, classify the studies, rate the studies on the basis of quality, rate the studies on the basis of the strength of their body of evidence, and report the studies' rank order. The terms “substance” and “disease or health-related condition” are defined by regulation. Only studies conducted in “healthy populations” are considered, because health claims are directed to the general population or designated subgroups (e.g., elderly persons) and are intended to assist the consumer in maintaining healthful dietary practices. A healthy population can be one at high risk for but without a diagnosis of the disease that is the subject of the health claim. Two recent publications provide examples of how the FDA has implemented this guidance. In the first case, the FDA concluded that no credible evidence exists for a health claim about the intake of lutein or zeaxanthin (or both) and the risk of age-related macular degeneration or cataracts [7]. In the second case, the FDA concluded that the relationship between chromium picolinate intake and insulin resistance is highly uncertain [8]. In both cases, qualified health claims were permitted.

Structure/function claims, such as “calcium builds strong bones,” describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans [9]. In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function (e.g., “fiber maintains bowel regularity”), or they may describe a feeling of general well-being purported to be associated with consumption of a nutrient or dietary ingredient. Structure/function claims may also describe a benefit related to a nutrient-deficiency disease (e.g., “consumption of vitamin C prevents scurvy”), as long as the statement includes how widespread the disease is in the United States. The Dietary Supplement Health and Education Act of 1994 established regulatory procedures for how such claims may appear on dietary supplement labels [10]. These claims must be truthful and must not be misleading, and they are not preapproved by the FDA (i.e., the manufacturer is responsible for ensuring the accuracy and truthfulness of the claims). Because structure/function claims can legally be made only about a drug, dietary supplement labels that include such a claim must contain the following statement: “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” [10]. Manufacturers of dietary supplements that make structure/function claims on labels or in product labeling must submit a notification to FDA no later than 30 days after marketing the dietary supplement that includes the text of the structure/function claim.

Unlike labels for dietary supplements, labels for conventional foods can carry structure/function claims and health claims only if the effects or benefits are derived from the nutritive value of the food. Dietary supplement claims can focus on nutritive as well as nonnutritive effects. In addition, disclaimers are not required for conventional foods, and manufacturers are not required to notify the FDA about structure/function claims [9]. To distinguish a dietary supplement from a conventional food, the Dietary Supplement Health and Education Act requires that the phrase “dietary supplement” appear as part of the product name on the front panel of product labels; however, the term “dietary” can be replaced by a descriptive phrase, such as “multivitamin and mineral” [10]. The Dietary Supplement Health and Education Act also defines what a dietary supplement is.

Under current FDA policy, the health benefits attributed to a food must be derived from its “nutritive value” for the food to be exempt from regulation as a drug. The FDA states that a food has “nutritive value” if it has “a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy” [3]. Many in the food industry would like a broader interpretation of the term that encompasses the increasing scientific knowledge of the role that foods and food components play in disease prevention and health promotion. For example, the Institute of Food Technologists Expert Panel recommends that the FDA expand the definition to include “the provision of a physical or physiological effect that has been scientifically documented or for which a substantial body of evidence exists for plausibility” [11].

Nutrient content claims describe the level of a nutrient, using terms such as “free,” “high,” and “low,” or they compare the level of a nutrient in one food to that in another food, using terms such as “more,” “reduced,” and “lite” [6, 12, 13]. Most regulations for nutrient content claims apply only to nutrients or substances that have an established daily value. The term “healthy” has been defined by regulation as an implied nutrient content claim. A product making a “healthy” claim must have healthy levels (as specified in the regulation) of total fat, saturated fat, cholesterol, other nutrients, and sodium [14]. The FDA exercises its oversight in determining, by means of the following Acts, which nutrient content claims may be used on a label or in labeling: (1) the Nutrition Labeling and Education Act, by issuing a regulation authorizing a nutrient content claim, and (2) the FDA Modernization Act, by prohibiting or modifying by regulation a nutrient content claim ≤120 days after receipt of a nutrient content claim notification.

Dietary guidance statements can also be made on food labels. Although health claims describe the relationship between a substance (i.e., a specific food or food component) and a disease or health-related condition, dietary guidance statements do not contain both elements [6]. Dietary guidance statements tend
to focus on general dietary patterns, practices, and recommendations that promote health. Typically, dietary guidance statements refer to a category of foods rather than to a specific substance. Dietary guidance statements can be made without FDA review or authorization before use, but the statements must be truthful and must not be misleading. A classic example is the dietary guidance message from the National Cancer Institute, which states that “[d]iets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic diseases” [5].

Probiotics are available to consumers mainly in the form of dietary supplements and conventional foods (e.g., yogurt) [15, 16]. The most common claims seen in the marketing of probiotics in the United States are structure/function claims. Health claims are not used, because the FDA has not approved these types of claims. In addition, nutrient content claims cannot be made, because a daily value has not been established for probiotics. Examples of structure/function claims currently seen in the probiotics marketplace are claims for strengthening the body’s defenses, caring for the digestive system, enhancing “joie de vivre,” helping naturally regulate the digestive tract, and helping regulate the digestive system by helping reduce long intestinal transit time.

The claims that can be made on labels of foods and dietary supplements have evolved over the years because of several congressional and legal decisions. Health claims authorized by the Nutrition Labeling and Education Act are the most definitive statements about the relationship between a food substance and a disease or health-related condition. Consumers do not rate these statements as most appealing, because the statements do not contain qualifying language that reflects the state of the science about the relationship between the nutrients and diseases or health-related conditions [17]. The FDA is currently evaluating findings from research on consumer perceptions of health claims. The FDA will use the results of this evaluation to determine how to modify the wording of health claims to ensure that they are appealing, are truthful, and do not mislead consumers.

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References


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References