



FOOD AND DIETARY SUPPLEMENT REGULATIONS COMPARED

Food and dietary supplements are both regulated by the U.S. Food and Drug Administration.

DIETARY SUPPLEMENT REGULATIONS IN BRIEF

INGREDIENTS

The term “dietary supplement” means a product intended to supplement the diet that contains one or more dietary ingredients. A dietary ingredient is a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of the above dietary ingredients. Dietary ingredients are customarily categorized as either “old” or “new” dietary ingredients.

The term “new dietary ingredient” means a dietary ingredient that was not marketed in the United States before October 15, 1994. Old ingredients (sometimes referred to as “grandfathered” ingredients) were marketed in the United States before that date and are generally considered safe unless the FDA demonstrates they are not. A firm planning to market a dietary supplement that contains a new dietary ingredient, unless exempt, must submit to FDA, at least 75 days before the dietary ingredient is introduced into interstate commerce, information that is the basis on which it has concluded that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe. FDA may object to the notification.

MANUFACTURING STANDARDS

The dietary supplement current good manufacturing practice (CGMP) rule (21 CFR Part 111) requires persons who manufacture, package, label, or hold a finished dietary supplement to establish and follow CGMPs to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. While manufacturers of the finished products are held to the CGMP requirements for dietary supplements, manufacturers of dietary ingredients that will be used in finished dietary supplements are required to follow good manufacturing practices for food (21 CFR Part 117).

The regulations for dietary supplements require manufacturers ensure the identity, purity, quality, strength and composition of both their ingredients and their finished dietary supplements. The regulations include the 100% identity testing requirement for incoming raw materials and finished product testing to ensure identity, purity, quality, strength and composition of dietary supplements. In addition, the regulations impose requirements for sanitary practices, proper training of personnel, cleaning of equipment and in-process controls to ensure consistency of product quality.

SAFETY

The manufacturer, packer, or distributor whose name and address appear on the label of a dietary supplement marketed in the United States is required to submit to FDA within 14 days all serious adverse events reported to the company as being associated with use of the dietary supplement in the United States. It must maintain records of all non-serious adverse events reported to it and make these records available to FDA upon request.

Most aspects of the FDA Food Safety Modernization Act (FSMA), signed into law by President Obama on January 4, 2011, apply to dietary supplements and their ingredients. The law enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides FDA with new enforcement authorities (e.g., mandatory recall authority) designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur.

CLAIMS

Claims that can be used on food and dietary supplement labels fall into four categories: nutrient content claims, nutrient deficiency claims, structure/function claims and health claims. The responsibility for ensuring the validity of these claims rests with the manufacturer. FDA has responsibility for enforcement of claims that appear on product labeling; the Federal Trade Commission enforces claim substantiation with respect to advertising. Manufacturers of dietary supplements who make structure/function claims must submit a notification to FDA within 30 days of first marketing the product that the claim is being used. If a dietary supplement label includes such a claim, it must provide a “disclaimer” that FDA has not evaluated the claim. The disclaimer must also state that the dietary supplement is not intended to “diagnose, treat, cure or prevent any disease,” because only a drug can legally make such a claim. Health claims (those that indicate a link with a reduction in disease risk) require the premarket approval of FDA before use.



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Conventional food items do not require FDA approval. However, any substance that is intentionally added to conventional food is a food additive that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or if it was commonly used in food before January 1, 1958.

Food companies may determine that ingredients are generally recognized as safe (GRAS) without informing or obtaining authorization from FDA. FDA does not approve GRAS substances. While the agency historically had a process by which it would affirm a company's GRAS determination, in 1997 it established a GRAS notification program through which a company may voluntarily inform FDA of a determination that the use of a substance is GRAS. GRAS (whether determined privately or as the subject of a GRAS notification) is established through consensus among experts qualified by scientific training and experience to evaluate its safety under the conditions of its intended use.

Food ingredients that are not GRAS are subject to premarket approval by FDA. Petitions for food additives are approved only for the specific uses that are presented to FDA. Foods may only contain approved food additives or GRAS substances. A number of dietary ingredients that are permissible in dietary supplements (e.g., melatonin) are not approved food additives or established to be GRAS for use in food and may not be contained in a conventional food product.

MANUFACTURING STANDARDS

Current good manufacturing practices (CGMPs) for food (21 CFR 117) describe the methods, equipment, facilities, and hazard analysis, and risk-based preventive controls for producing processed food. As the minimum sanitary and processing requirements for producing safe and wholesome food, they are an important part of regulatory control over the safety of the nation's food supply and help prevent spoilage, contamination and adulteration of food. These regulations include CGMPs (sanitary practice requirements for personnel, buildings, facilities, and equipment, and production and process controls), and the implementation of a food safety plan.

SAFETY

FDA's Reportable Food Registry is an electronic portal for industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences. The Reportable Food Registry helps FDA better protect public health by tracking potential food outbreaks, patterns, and targeting inspections. It differs from adverse event reporting for dietary supplements in that these reports are intended to be preventive when a manufacturer has reason to believe an adulterated product has entered the market (whether any harm has in fact occurred); by contrast, adverse event reports for dietary supplements result from a consumer experience that leads to an adverse event being reported to the company, a medical professional or FDA.

The FDA Food Safety Modernization Act (FSMA), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by strengthening the food safety system. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides FDA with new enforcement authorities (e.g., mandatory recall authority) designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. Most aspects of FSMA are applicable to both foods and dietary supplements.

CLAIMS

Claims that can be used on food are similar to those that are permissible for dietary supplements: nutrient content claims, nutrient deficiency claims, structure/function claims, health claims and dietary guidance statements. The responsibility for ensuring the validity of these claims rests with the manufacturer. FDA has responsibility for enforcement of claims that appear on product labeling; the Federal Trade Commission enforces claim substantiation with respect to advertising. Unlike dietary supplements, traditional food items that make structure/function claims are not required to notify FDA of these claims or to provide the disclaimer statements on these products. Foods, like supplements, may not make claims to diagnose, treat, cure or prevent any disease. Health claims (those that indicate a link between food and a reduction in a disease risk) require the premarket approval of FDA before use.