



# Key Questions About Dietary Supplements and Their Regulation

## WHAT ARE DIETARY SUPPLEMENTS?

Dietary supplements are products which contain one or more dietary ingredients such as vitamins, minerals, herbs or other botanicals or amino acids used to supplement the human diet. Today, more than 70 percent of Americans trust dietary supplements and use them as a way to complement inadequate diets and maintain a healthy lifestyle. Some of the most commonly used supplements include daily multi-vitamins, fish oil, vitamin D supplements and probiotics.

## ARE DIETARY SUPPLEMENTS REGULATED?

**Yes.** The Food and Drug Administration (FDA), the Federal Trade Commission (FTC), as well as one or more government agencies in each of the 50 states regulate dietary supplements. Legal authority to conduct this oversight comes through the Federal Food, Drug and Cosmetic Act (FDCA), the FTC Act and various state health and consumer protection laws. The Dietary Supplement Health and Education Act (DSHEA) passed unanimously by both houses of Congress in 1994 further strengthened regulations of dietary supplements. FDA is charged with inspecting manufacturing facilities, reviewing labeling and monitoring products for safety. FTC pursues deceptive, false and misleading advertising. States inspect supplement manufacturing facilities and enforce consumer protection laws.



## DOES FDA HAVE AUTHORITY TO ASSURE THAT DIETARY SUPPLEMENTS ARE SAFE?

**Yes.** Current law provides FDA with ample authority to assure the safety of dietary supplements. All new ingredients marketed after 1994 must submit a formal 75-day notice along with evidence that the product is reasonably expected to be safe. This is referred to as a new dietary ingredient (NDI) notification. If FDA has concerns about the ingredient or its safety profile, the agency has clear authority to request more information or to reject the notification and deny the product's entry into the market. Since the passage of DSHEA, FDA has rejected approximately 70% of the NDI notifications filed.

Once a dietary supplement enters the stream of commerce, the FDA may remove a product if it is "adulterated" or "misbranded." A product is considered adulterated if it contains unlisted ingredients or is not prepared or packaged under good manufacturing conditions. It is misbranded if its labeling is false or misleading. In either case, FDA has authority to seize and destroy the product, impose fines or even imprisonment. In addition, FDA can remove a product from the market if it "presents a significant or unreasonable risk of illness or injury" under conditions of use recommended in its labeling. A separate provision gives FDA authority to declare a product "an imminent hazard to public health or safety." FDA can also request manufacturers to modify products and claims or to provide warnings to consumers. In addition, FDA now has mandatory recall authority that enables it to force a dietary supplement manufacturer to immediately remove a product from the marketplace.

FDA also inspects dietary supplement manufacturers to assure compliance with good manufacturing practices (GMPs). These rigorous practices impose higher standards on dietary supplements than those applied to conventional foods. Dietary supplement GMPs include requirements for identity testing for all ingredients as they arrive at the manufacturer's site. Manufacturers must qualify their suppliers before receiving goods, incoming ingredients must be quarantined until their identity is confirmed using scientifically valid methods of analysis, and all components of dietary supplements must meet specifications established by the manufacturer regardless of where the ingredient was sourced. During an inspection, FDA has access to all the manufacturers' records, including access to the country of origin of all supplement ingredients. All parties in the production and distribution of dietary ingredients must keep records of suppliers and customers ("one up and one down") that permit the agency to trace the pedigree of ingredients back to their original source. In addition, the GMPs require manufacturers to meet standards for sanitation, batch records for production, employee training, validation of manufacturing procedures, and testing final products for conformance with the label.

## HOW ARE DIETARY SUPPLEMENT LABELING AND CLAIMS REGULATED?

Dietary supplements are required to have a standard Supplement Facts box on the labeling that describes the suggested use, serving size, amount per serving, percentage of the daily value and list of ingredients. If the label does not provide this information along with the quality and quantity of ingredients, then the product is misbranded and subject to penalties.



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The law permits supplements to use certain truthful, non-misleading and substantiated claims, including:

- **Structure/function** claims that describe effects of the product on the body may be made (e.g. calcium helps build and support strong bones). A disclaimer must be added to a product's label stating that the structure/function claim "has not been evaluated by" FDA.
- **Health claims** that describe the relationship between a substance and a disease (e.g., folic acid can reduce the risk of neural tube birth defects). These claims *must* be submitted to and approved by FDA and be supported by "significant scientific agreement." FDA has approved a handful of health claims for key ingredients like calcium and vitamin D, folic acid, and psyllium (fiber).
- **Qualified health claims** may also be approved by FDA when there is strong evidence of a health benefit, but not complete scientific agreement, if qualifying language can be developed that truthfully describes the state of the evidence.

Advertising for dietary supplements is regulated by the FTC. It imposes a similar standard, asking if the claims in an ad are truthful, not misleading and adequately substantiated. Armed with the ability to impose civil fines, disgorgement of profits, and restitution to consumers, FTC frequently brings enforcement actions against dietary supplement ads that are not in compliance.

## HAS CONGRESS PASSED ANY NEW LAWS IMPACTING DIETARY SUPPLEMENTS SINCE DSHEA?

**Yes.** Congress has passed substantial additional requirements on dietary supplements and additional authority for FDA and other agencies to regulate these products. Among these laws:

- **Bioterrorism Act (2002)** required dietary supplement manufacturers to register with the FDA and imposed new ingredient tracking requirements.
- **Dietary Supplement and Non-Prescription Drug Consumer Protection Act (2006)** required manufacturers to report information they receive about all serious adverse events to FDA.
- **Food Safety Modernization Act (2010)** provided FDA mandatory recall authority, required annual registration with FDA, required verification of ingredient suppliers and required FDA to notify the Drug Enforcement Agency (DEA) when it identifies a new dietary ingredient that it believes is a steroid.
- **Designer Anabolic Steroid Control Act (2014)** Closed a loophole that often kept criminals selling illegal steroids (often masquerading as dietary supplements) to escape prompt detection and removal by DEA. It also increased criminal and civil penalties.

## ARE THERE ALSO VOLUNTARY PROGRAMS THAT THE DIETARY SUPPLEMENT INDUSTRY HAS TO ENSURE QUALITY AND PREVENT MISLEADING CLAIMS?

**Yes.** The FTC's efforts to protect consumers from deceptive advertising are supplemented by a voluntary industry program of the National Advertising Division (NAD) of the Council of Better Business Bureaus (CBBB), funded by industry. This program reviews supplement advertising and makes recommendations for modification or withdrawal of ads that may be deceptive.

**Yes.** A number of supplement manufacturers subject their products to verification and quality control tests by independent third party organizations such as the widely respected U.S. Pharmacopeia (USP). In addition to complying with all applicable government regulations, USP verified dietary supplements must pass a stringent set of tests that ensure product purity and quality. USP verifies that the product: (1) contains the ingredients listed on the label in declared potency and amounts (2) is free of harmful levels of specified contaminants (3) the ingredients will release and dissolve so they are available for the body to absorb and (4) has been made according to FDA GMPs. Products passing these rigorous tests may bear a label certifying their verification as an added indication of quality and safety to consumers.



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