



BACKGROUND

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Is Your Dietary Supplement *Really* Regulated?

Dietary supplements – vitamins, minerals, botanicals, sports nutrition, weight management and specialty supplements (such as glucosamine/chondroitin and omega-3 fatty acids, to name just a few) – **are regulated**. The Food and Drug Administration (FDA), the Federal Trade Commission (FTC), and state agencies have clear authority over dietary supplements through the Federal Food, Drug and Cosmetic Act (FDCA) and the FTC Act. FDA is charged with inspecting manufacturing facilities, reviewing labeling and monitoring products for safety. FTC pursues deceptive, false and misleading advertising. Claims that dietary supplements are not regulated or are “loosely” regulated are inaccurate. Dietary supplements have always been regulated, and are more rigorously regulated today than they were even five years ago.

How Do You Know Supplements Are Safe?

The FDCA, as amended by the Dietary Supplement Health and Education Act (DSHEA), established that dietary supplements that were in commerce prior to 1994 have a history of safe use, and therefore, can remain on the market without additional safety review. All new ingredients marketed after that date, however, 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. It is patently illegal to add a prescription drug or an anabolic steroid to a product and call it a “dietary supplement.”

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, the agency has enforcement 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.” In lesser dramatic situations, FDA can request manufacturers to modify products and claims or to provide warnings to consumers. While mandatory recall authority is not currently available, a request from FDA to recall a product from the marketplace voluntarily is viewed seriously by manufacturers and is usually implemented quickly.

How Do You Know Supplements Do What the Label Says?

Some people think a supplement producer can put whatever they want on a label – that’s just not true! Providing consumers with information about a product’s uses is an important aspect of consumer education, but it is equally important that manufacturers and marketers ensure that the claims they make about their products are truthful, and not misleading. 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.

When describing a dietary supplement’s benefits, the law permits products to use certain claims, provided there is appropriate scientific support. The FDCA allows products to make nutrient content, structure/function, and health claims. **Nutrient content** claims characterize the level of vitamins and minerals in the product. **Structure/**

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function claims describe effects of the product on the body. However, the law requires these claims must have substantiation (i.e., scientific support) that the claim is truthful and not misleading; FDA must be informed of these claims; and it may request to review the substantiation. A disclaimer must be added to a product's label stating that the structure/function claim "has not been evaluated by" FDA. **Health** claims 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). FDA may also consider granting **qualified health** claims when there is some evidence of a health benefit, but not complete scientific agreement, if qualifying language can be developed that truthfully describes the state of the evidence.

In addition, the FTC regulates advertising for dietary supplements. 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 go too far. The FTC's efforts are supplemented by a voluntary industry program of the National Advertising Division (NAD) of the Council of Better Business Bureaus (CBBB), funded by CRN, that reviews supplement advertising and makes recommendations for modification or withdrawal of ads that may be deceptive.

How Do You Know the Ingredients Are Pure and Uncontaminated?

Good manufacturing practices (GMPs) for dietary supplements are specific rules for the manufacturing processes of vitamins, minerals, herbs and botanicals, amino acids and all other supplements. Finalized in 2007, these rigorous practices impose higher standards on dietary supplements than food GMPs applied to conventional foods. Dietary supplement GMPs include thorough 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.

Manufacturers are accountable to FDA for the manufacturing process as well as the ingredients. During an inspection, FDA has access to all the manufacturers' records, including access to the country of origin of all supplement ingredients. The existing bioterrorism law already requires all parties in the production and distribution of dietary ingredients to 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 GMP rules examine sanitation, batch records for production, employee training, validation of the manufacturing procedures, and testing final products for conformance with the label.

If There Are Problems or Concerns, How Does FDA Know?

It's important to note that pre-market approval is no guarantee of safety, as witnessed by other FDA-regulated products that have been approved by FDA, only to be later recalled due to safety concerns. That's why post-market surveillance is so important. Dietary supplements do not undergo pre-market approval, but a law enacted in 2006 requires manufacturers to report information they receive about all serious adverse events to FDA. A "serious adverse event" is a negative health-related experience such as hospitalization. This information alerts FDA to possible signals of a problem and could identify concerns with ingredient safety, manufacturing issues, contamination (of either raw ingredients or finished products), tamperings, and bio-terrorism. The fact that there are relatively few adverse events reported for dietary supplements (compared to other FDA-regulated products) demonstrates the wide margin of safety for this category of FDA-regulated product. But if there is a concern, adverse event reporting gives FDA an early warning of the potential problem.

*FDA states that **dietary supplements are regulated** under a "different set of regulations from those covering 'conventional food' and drug products" but this does not mean they are unregulated. In fact, with over 150 million Americans using dietary supplements annually with little problem, it is clear that supplements are held to strict requirements, ensuring their safety and efficacy.*