



Regulation of Dietary Supplements Overview

Background

Dietary supplements are regulated as a unique category of food by the U.S. Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act (FFDCA) as amended by the Dietary Supplement Health and Education Act (DSHEA) of 1994.

Additionally, advertising of dietary supplements is subject to consumer protections under the Federal Trade Commission Act, enforced by the Federal Trade Commission (FTC).

The Natural Products Association (NPA) supports the strong enforcement of these regulations in a clear and consistent manner.

Regulations governing dietary supplements include the following:

Product Integrity and Manufacturing

Supplement manufacturers must adhere to strict current Good Manufacturing Practices (cGMP) established by the FDA, requiring identity, strength (potency), and contaminant testing on all ingredients, with additional testing requirements for finished products.

As of June 2010, all manufacturers fall under Good Manufacturing Practice (GMP) regulations and the FDA has begun conducting extensive cGMP inspections to ensure compliance.

Manufacturers can only use ingredients that are federally sanctioned either through (a) premarket review by the FDA as a New Dietary Ingredient (NDI), with a dossier showing safety and other required data (the FDA has rejected numerous submissions); (b) proof that the ingredient was marketed as a dietary supplement in the United States prior to October 15, 1994; or (c) proof that it was previously used in food with no chemical alteration.

No pharmaceuticals, including steroids, may be used in dietary supplements.

Dietary supplement manufacturers, packers, distributors, and marketers are required to report to the FDA any information regarding serious adverse events that might be associated with the use of their product. Manufacturers must keep records of all adverse events, including non-serious events, for six years.

Manufacturers, like all other food manufacturers, must register with the government and give advance notification of raw materials imports.

Claims

Supplement labels and advertising may not claim to treat, cure or prevent any disease (other than as noted below). The great majority of supplement claims describe the role of the supplement in promoting healthy human body structure or function. Those claims must be truthful (the manufacturer is responsible for their accuracy) and not misleading, and must carry a disclaimer that the FDA has not approved the claim. Such claims must be provided to the FDA along with a copy of the product label within 30 days of marketing the product.

About the Natural Products Association

Founded in 1936, the Natural Products Association (NPA) is the nation's largest and oldest nonprofit organization dedicated to the natural products industry. NPA represents over 1,400 members accounting for more than 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, and health/beauty aids. The association supports a strong grassroots network of members and consumers who are passionate about products that contribute to healthier lifestyles.

Headquartered in Washington, DC, NPA has been the leading industry watchdog for 80 years, acting as an advocate on regulatory and legislative issues affecting natural products.

FDA-specified health claims for foods and dietary supplements are permitted in accordance with FDA's Significant Scientific Agreement (SSA). Health claims found in Title 21 of FDA's codified Federal Regulations describe reductions in disease risk for foods and supplements which meet the claim's requirements.

Retailers may provide customers with "third party literature" discussing how a supplement can be useful in the prevention or treatment of a disease if the literature presents a balanced view of the available science (i.e. describes positive, negative, and neutral studies regarding an ingredient's effect), does not mention a specific product brand, is physically separate in the store from the product it describes, and meets other conditions.

Labeling

All dietary supplement ingredients must be listed on the label and the product must meet the strength, quality, and purity levels the supplement is represented to have.

Labels must provide the product name, net quantity of contents, and manufacturer or distributor's name and address.

The label must disclose the major allergens responsible for most food allergies.

Relevant Laws

DSHEA

Amends the FFDCFA to create the framework for the regulation of supplements as a category of food. Most regulations governing the manufacture and sale of supplements stem from DSHEA.

Federal Trade Commission Act of 1914

Governs the marketing and advertising of dietary supplements.

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Requires all food manufacturers to register with the government and give advance notification of raw material imports.

Anabolic Steroid Control Act of 2004

Bans steroid precursors sold as dietary supplements.

Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006

Requires reporting of all serious adverse events for both dietary supplements and over-the-counter drugs.

FDA Food Safety Modernization Act of 2010

Among other provisions, provides the FDA with mandatory recall authority for all foods, expands facility registration obligations, and requires the FDA to issue a draft NDI guidance.

NPA Position

NPA maintains the framework for dietary supplement regulation is sound and DSHEA gives the FDA adequate tools to go after unsafe supplements.

NPA continues to oppose any legislation that seeks to create redundant regulation for the dietary supplement industry or create more bureaucracy for an already resource-challenged agency while failing to produce safer products.

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