Dietary Supplement Regulation

November 21, 2025
By Michael H. Cohen

The Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) primarily oversee dietary supplement regulation in the United States. While the FDA regulates dietary supplement labeling, manufacturing, and safety, the FTC monitors advertising to ensure marketing claims are truthful and not misleading. Together, these agencies protect consumers and uphold public health standards under laws such as the Dietary Supplement Health and Education Act (DSHEA) and the Federal Food, Drug, and Cosmetic Act.

In this post, we'll explore how dietary supplements are regulated and what labeling and packaging requirements apply. We'll also cover key considerations for dietary ingredient notifications and good manufacturing practices (GMPs).

What Are Dietary Supplements?

According to the Food and Drug Administration (FDA), dietary supplements are products intended to supplement the diet and contain one or more dietary ingredients. These could include vitamins, minerals, herbs or other botanicals, amino acids, or other substances that add nutritional value to the diet.

Under U.S. dietary supplement regulation, these products are classified as a special category of food rather than drugs. This means they are not approved by the FDA before marketing. Instead, manufacturers are responsible for ensuring their products are safe, properly labeled, and compliant with FDA regulations and good manufacturing practices (GMPs).

The Federal Trade Commission (FTC) also plays a role by overseeing dietary supplement advertising law. They ensure that any health or structure/function claims are truthful and supported by scientific evidence. Common claims include structure/function claims like "calcium builds strong bones" or "fiber maintains bowel regularity," which describe how a dietary ingredient affects the body's structure or function without suggesting disease prevention or treatment.

Types of Dietary Supplements

1. **Vitamins and Minerals**: These are the most widely used supplements, addressing nutrient deficiency diseases and promoting overall wellness. Examples include vitamin C, which supports immune health, and calcium, known for maintaining bone strength.
2. **Herbal Products**: Derived from plants, these supplements may include ginseng, echinacea, or turmeric, often used for their potential health benefits related to energy, immunity, and inflammation.
3. **Amino Acids and Protein Supplements**: Popular among athletes and fitness enthusiasts, these supplements support muscle recovery and growth by supplying essential amino acids.

4. **Probiotics and Enzymes**: These products aid digestion and promote gut health by supporting the balance of beneficial bacteria and enzyme activity.

Dietary supplements are commonly used to enhance nutrition, support specific health goals, or address dietary gaps that may exist in the food supply. The industry continues to grow rapidly as consumers seek natural products to maintain wellness and prevent nutrient deficiencies. However, because supplements are regulated differently than drugs, understanding FDA and FTC dietary supplement regulation is critical to avoid safety risks and ensure compliance in labeling, packaging, and marketing.

Key Regulatory Agencies for Dietary Supplement Oversight

In the United States, the regulatory framework for dietary supplements aims to safeguard consumers and foster innovation and market expansion. Several agencies share responsibility for ensuring that dietary supplement labeling, advertising, and manufacturing practices meet federal safety and transparency standards. The two primary authorities (the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC)) play distinct but complementary roles in overseeing the dietary supplement industry.

FDA (Food and Drug Administration)

The FDA regulation oversees most aspects of dietary supplement regulation, including labeling, manufacturing, packaging, and safety monitoring. Under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Dietary Supplement Health and Education Act (DSHEA), dietary supplements are treated as a special category of food rather than drugs. This distinction means that the FDA does not approve dietary supplements before they reach the market, unlike pharmaceuticals, which require premarket approval and clinical trials demonstrating safety and efficacy.

However, dietary supplement manufacturers must ensure their products are safe and properly labeled. The FDA enforces good manufacturing practices (GMPs) to prevent contamination and mislabeling, requires new dietary ingredient notifications (NDINs) when introducing novel ingredients, and regulates claims made on Supplement Facts panels. The agency also evaluates structure/function claims, nutrient content claims, and health claims to ensure they are not misleading and are supported by significant scientific agreement or credible research.

FTC (Federal Trade Commission)

While the FDA governs product labeling, the FTC oversees dietary supplement advertising law, ensuring that promotional materials are truthful, substantiated, and not deceptive. The FTC's authority extends to marketing claims that promise disease prevention, weight loss, or enhanced performance without credible scientific backing.

For example, the FTC has taken enforcement actions against companies making false claims such as "clinically proven to cure cardiovascular disease" or "burns fat without diet or exercise." These cases illustrate the importance of substantiated structure/function claims and transparent disclosures in advertising. Compliance with FTC standards protects consumers and reduces the risk of costly legal penalties and reputation damage for supplement companies.

Other Agencies and International Oversight

In addition to federal oversight, some state-level regulations govern the sale and labeling of dietary supplements within specific jurisdictions, particularly concerning consumer protection and product safety. Internationally, countries such as Canada and members of the European Union (EU) have their own frameworks for regulating food and dietary supplement products. For instance, the European Food Safety Authority (EFSA) evaluates health and nutrition claims, while Health Canada enforces labeling and safety standards for natural health products.

Dietary Supplement Regulation Laws and Guidelines

The regulatory landscape for dietary supplements in the United States is shaped by a combination of federal laws, agency

guidelines, and enforcement policies. Key statutes and standards include the Dietary Supplement Health and Education Act (DSHEA), current Good Manufacturing Practices (cGMPs), and labeling and health claims regulations enforced by the FDA and FTC.

Dietary Supplement Health and Education Act (DSHEA)

Enacted in 1994, the Dietary Supplement Health and Education Act (DSHEA) provides the primary framework for dietary supplement regulation in the U.S. DSHEA defines what constitutes a dietary supplement, sets labeling requirements, and distinguishes supplements from conventional foods and pharmaceuticals. Under DSHEA, manufacturers can legally market supplements containing dietary ingredients such as vitamins, minerals, herbs, amino acids, and other substances intended to supplement the diet.

DSHEA allows companies to make structure/function claims such as “calcium builds strong bones” or “fiber maintains bowel regularity.” However, DSHEA restricts disease claims, which suggest a supplement can prevent, treat, or cure a specific disease (e.g., “reduces risk of cardiovascular disease”). Products making disease claims are considered drugs under the FD&C Act and require premarket approval.

Current Good Manufacturing Practices (cGMP)

To ensure product quality and safety, the FDA enforces current Good Manufacturing Practices (cGMPs) for dietary supplements. These standards cover every stage of production, including ingredient sourcing, manufacturing, packaging, labeling, and storage.

cGMPs require companies to maintain detailed records, conduct identity testing of ingredients, and implement quality control measures to prevent contamination, adulteration, and mislabeling. Compliance with cGMPs helps ensure that supplements meet safety requirements and accurately reflect what is stated on the product label.

Labeling and Health Claims Regulations

Dietary supplement labels must include a Supplement Facts panel, ingredient list, serving size, and the name and address of the manufacturer. Health-related claims on labels are strictly regulated:

- **Structure/function claims**: This category describes the effect of a dietary ingredient on the body’s structure or function (e.g., “Vitamin C supports immune health”). These claims must include the FDA-required disclaimer 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.”
- **Disease claims**: This clause suggests that a supplement that can treat, prevent, or cure a disease is prohibited unless the product is reviewed and approved as a drug by the FDA.

How Dietary Supplements Are Monitored

Unlike pharmaceuticals, dietary supplements do not require FDA approval before being marketed and sold to consumers. This means manufacturers are responsible for ensuring that their products are safe, accurately labeled, and compliant with dietary supplement regulation before they enter the market. While pre-market approval is not required, companies must comply with current Good Manufacturing Practices (cGMPs), maintain proper records, and ensure that labeling and structure/function claims meet FDA and FTC regulations.

Post-market monitoring is a critical component of supplement oversight. **The FDA relies on manufacturers, healthcare providers, and consumers to report adverse events associated with supplement use.** This reporting system allows the agency to identify potential safety risks, evaluate patterns of harm, and take action when necessary.

In cases where products are found to be unsafe, contaminated, or mislabeled, the FDA can issue voluntary recalls in cooperation with manufacturers or, in more serious situations, enforce mandatory recalls. The FDA has removed numerous

supplements from the market due to their undeclared ingredients, harmful contaminants, or unsubstantiated claims, underscoring the importance of vigilant post-market monitoring.

In addition to federal oversight, many supplement manufacturers participate in third-party certification programs to demonstrate quality and safety. Organizations such as USP (United States Pharmacopeia), NSF International, and other recognized quality seals test products for ingredient accuracy, purity, and manufacturing standards. These certifications give consumers more peace of mind that the supplement meets safety and quality standards. By combining regulatory compliance with third-party verification, the dietary supplement industry can better protect public health while promoting transparency and trust in the marketplace.

Best Practices for Consumers

Choosing safe and effective dietary supplements requires careful attention to labeling, claims, and regulatory compliance. **Start by reading the product label thoroughly, paying close attention to the Supplement Facts panel, dietary ingredients, serving sizes, and any structure/function or health claims**. Be wary of products that make unverified promises about preventing, treating, or curing specific diseases, as these are often outside the bounds of FDA and FTC dietary supplement regulation.

Look for third-party certifications from organizations like USP or NSF, which test supplements for purity, ingredient accuracy, and adherence to current Good Manufacturing Practices (cGMPs). These seals provide added assurance that the product meets established quality standards and is less likely to contain contaminants or misrepresented ingredients.

Consumers should also remain proactive in protecting their health by **reporting adverse effects from supplements to the FDA or other regulatory bodies**. Timely reporting helps authorities monitor safety risks and enforce recalls when necessary.

For individuals navigating complex situations, such as misleading labeling or safety concerns, **hiring a healthcare lawyer** with expertise in dietary supplement regulation can provide guidance, protect legal rights, and ensure compliance with federal and state laws. By following these best practices, consumers can make informed decisions and safely incorporate supplements into their wellness routine.

Unsure If Your Supplement Meets Regulatory Standards?

Navigating dietary supplement regulation can be complex, but understanding the rules is essential for both consumer safety and legal compliance. From DSHEA and FDA labeling requirements to structure/function claims, good manufacturing practices (cGMPs), and FTC advertising regulations, knowing the regulatory framework helps ensure supplements are safe, accurately labeled, and marketed responsibly. Consumers and manufacturers alike benefit from reading labels carefully, checking for third-party certifications, and reporting any adverse effects to the appropriate authorities.

FAQs

These FAQs provide quick guidance on FDA oversight, labeling, safety, and best practices for choosing or marketing supplements.

Are Dietary Supplements FDA-Approved?

No, dietary supplements do not require FDA approval before being sold. The FDA regulates labeling, safety, and manufacturing practices, but it does not review supplements for efficacy like it does for drugs.

How Can I Report a Harmful Supplement?

You can report adverse events or safety concerns to the FDA through their Safety Reporting Portal. Reporting helps regulatory authorities monitor products and take action when necessary.

What Does “Third-Party Tested” Mean?

Third-party testing indicates that an independent organization, such as USP or NSF, has verified the supplement for ingredient accuracy and purity. This certification provides additional assurance that the product meets quality standards.

What Are Structure/Function Claims?

Structure/function claims describe how a dietary ingredient affects the body’s structure or function, like “fiber maintains bowel regularity.” They cannot claim to prevent, treat, or cure a specific disease without FDA approval.

Can Supplements Make Health Claims?

Yes, certain health claims are allowed if they are supported by significant scientific agreement or meet FDA standards. Claims must include required disclaimers to avoid misleading consumers.

Do I Need a Prescription for Dietary Supplements?

No, most dietary supplements are available over-the-counter and do not require a prescription. However, some specialty supplements with higher-potency ingredients may require professional guidance.

How Do I Know if a Supplement is Safe?

Check for cGMP compliance, read the label carefully, and look for third-party certifications like USP or NSF. Reporting any adverse effects and consulting a healthcare provider also helps ensure safety.

Are All Supplements Regulated the Same Way Internationally?

No, regulations vary by country. For example, the EU and Canada have different labeling, safety, and health claim requirements compared to the U.S. FDA and FTC rules.