HOW DIETARY SUPPLEMENTS ARE REGULATED

Dietary Supplements must be manufactured under the current Good Manufacturing Practices (DSHEA Sec. 9).

Labeling must bear a Supplement Facts table, including the name and quantity of each dietary ingredient (DSHEA Sec. 7).

Labeling may bear statements of nutritional support. Such statements must be adequately substantiated and may not claim to diagnose, mitigate, treat, cure, or prevent any disease. The manufacturer should notify the FDA of any such statements within 30 days of first marketing (DSHEA Sec. 6). Health claims must be pre-approved by FDA (NLEA).

Disclosure of key allergens is required (Food Allergen Labeling Act).

Dietary Supplements may only be intended for oral ingestion. They may not be represented for use as a conventional food and may not contain any drug substances (DSHEA Sec. 3).

Safety data regarding "new dietary ingredients" not previously present in the food supply must be submitted to FDA at least 75 days prior to marketing (DSHEA Sec. 8).

All ingredients must be safe for consumption (DSHEA Sec. 4 and Food Additive Regulations).

Accurate disclosure of contents is required (Fair Packaging & Labeling Act).

The label must state that the product is a "Dietary Supplement" (DSHEA Sec. 7 (a)).

Labeling must bear a phone number or address through which consumers can report serious adverse events (Dietary Supplement and Nonprescription Drug Consumer Protection Act).

Supplement manufacturers must register each facility with FDA (Bioterrorism Act).

Lot number control is required to enable product traceability (Dietary Supplements Good Manufacturing Practices).

Labels bearing statements of nutritional support must prominently display a prescribed disclaimer statement (DSHEA Sec. 6).

LAWS THAT DIRECTLY IMPACT DIETARY SUPPLEMENTS

- DSHEA: Dietary Supplement Health and Education Act
- NLEA: Nutrition Labeling and Education Act
- FFDCA: Federal Food, Drug, and Cosmetic Act
- Fair Packaging and Labeling Act
- Bioterrorism Act
- Food Allergen Labeling Act
- Dietary Supplement and Nonprescription Drug Consumer Protection Act
- FSMA: Food Safety Modernization Act

The United States Pharmacopeia (USP) sets official standards for dietary supplements. For products carrying the USP mark, USP has tested and verified ingredients, potency, and manufacturing processes. A supplement must conform to the specifications of an official compendium, if so represented. Otherwise, a supplement must meet the identity, strength, purity and composition as represented (DSHEA Sec. 7(a)).