Dietary Supplement Compliance in the U.S. – An Overview of Relevant Regulations

In the U.S., dietary supplements are regulated under the Dietary Supplement Health and Education Act (DSHEA) and overseen by the U.S. Food and Drug Administration FDA and the Federal Trade Commission (FTC).

Mandatory Labeling Requirements: Dietary supplements must adhere to strict labeling regulations, each of which have specific formatting requirements (21 CFR Part 101).

Dietary Supplement Claims: Claims made on supplements include Nutrient Content Claims, Health Claims and Structure/Function Claims. Each type of claims has specific criteria to meet and substantiation requirements. Structure/Function claims also trigger the FDA disclaimer on the label and notification to the FDA. All claims must be substantiated to avoid misleading consumers, and material information must be disclosed (Label Claims for Food & Dietary Supplements, 21 CFR Part 101 Subpart D, 21 CFR Part 101 Subpart E, 21 CFR 101.93).

Formula Compliance and Prohibited Ingredients: It is the importer, manufacturer or brand's responsibility to ensure that ingredients used comply with all regulations and are safe (Information on Select Dietary Supplement Ingredients and Other Substances).

New Dietary Ingredients (NDIs): Ingredients that have been identified as New Dietary Ingredients (NDIs) must undergo a notification process to the FDA which must include evidence of safety (21 CFR Part 190 Subpart B).

FDA Facility Registration: Facilities involved in supplement manufacturing, packing, holding or labeling must be registered with the FDA, and renew their registration in even-numbered years (21 CFR Part 1 Subpart H, Registration of Food Facilities).

cGMPs: Dietary supplements must be produced, handled and stored using Good Manufacturing Practices (cGMPs), designed to ensure the quality, purity, and safety of supplements (21 CFR Part 111).

Importer Compliance: Importers of dietary supplements must ensure that products meet FDA regulations, including cGMPs and Foreign Supplier Verification Program (FSVP) requirements (21 CFR Part 1 Subpart L), FSMA Final Rule on Foreign Supplier Verification Programs (FSVP).

Adverse Event Reporting: Manufacturers must report any Serious Adverse Events (SAEs) related to their products to the FDA, as well as follow recordkeeping requirements (Public Law 109-462).

Recall Preparedness: Manufacturers and importers should have a Recall Plan, which includes procedures for initiating a recall, defining roles, maintaining records, and establishing communication protocols (21 CFR Part 7 Subpart C).

Dietary Supplements Guidance Documents & Regulatory Information

FTC's Health Products Compliance Guidance