Dietary Supplement Labeling

Dietary supplements must be manufactured under the current Good Manufacturing Practices (DSHEA Section 9; 21 CFR 111).

Labeling must bear a Supplement Facts table, including the name and quantity of each ingredient (DSHEA Section 7; 21 USC 343(q)(5)(F)).

False or misleading labeling claims are prohibited (DSHEA Section 6; 21 USC 343(r)(6)(B)).

Health claims must be pre-approved by FDA and are subject to significant scientific agreement (NLEA; 21 USC 343(r)(3)(B)(i).

Labeling may bear statements of nutritional support (DSHEA Section 6; 21 USC 343(r)(6)(A)). These statements must be adequately substantiated and may not claim to diagnose, mitigate, treat, cure or prevent any disease (DSHEA Section 6; 21 USC 343(r)(6)(C)).

The manufacturer must notify FDA of these statements within 30 days of first marketing (DSHEA Section 6; 21 USC 343(r)(6))).

Disclosure of key allergens is required (Food Allergen Labeling Act; 21 USC 343(w)).

Dietary supplements may only be intended for oral ingestion (DSHEA Section 3; 21 USC 321(ff)(2)(A)). They may not be represented for use as a conventional food (DSHEA Section 3; 21 USC 321(ff)(2)(B)) and may not contain any drug substances (DSHEA Section 3; 21 USC 321(ff)(3)(B)).

Under the recommended conditions of use, a dietary supplement may not present significant or unreasonable risk of illness or injury (21 USC 342(f)(A)). Safety data regarding any "new dietary ingredients" must be submitted to FDA at least 75 days prior to marketing (DSHEA Section 8; 21 USC 350b(a)(2)).

All ingredients (including inactive ingredients) must be safe for consumption (DSHEA Section 4 and Food Additives Regulations; 21 USC 342(f)(1)).

Labels bearing statements of nutritional support must prominently display a prescribed disclaimer (DSHEA Section 6; 21 USC 343(r)(6)(C)).

Supplement manufacturers must register each facility with FDA (Bioterrorism Act; 21 USC 350d).

Labeling must bear a phone number or address through which consumers can report adverse events (Dietary Supplement and Nonprescription Drug Consumer Protection Act ; 21 USC 343(y)).

Lot number control is required to enable product traceability (Dietary Supplement Good Manufacturing Practices; 21 CFR 111.160(d)).

If expiration date is provided, it must be supported by acceptable data (Dietary Supplement GMP; 21 CFR Preamble).

A supplement may be certified for quality, i.e. conforming to GMP standards, by a reputable 3rd party certifier such as NSF or USP. These products will include a quality "seal" authorized by the certifier (21 USC 343(s)(2)(D)).

Accurate disclosure of contents is required (Fair Packaging and Labeling Act; 21 USC 343(e)(2)).

The label must state that the product is a "Dietary Supplement" (DSHEA Section 7(a); 21 USC 343(s)(2)(B)).

A dietary supplement is misbranded if it is represented to conform to specifications of an official compendium and fails to so conform (21 USC 343(s)(2)(D)).

SAMPLE SUPPLEMENT

HEALTHFUL HEALTH PRODUCTS

CALCIUM

500 mg+D+K

DIETARY SUPPLEMENT

Maximum strength for bone health.†

100 TABLETS

Adequate calcium and vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis

Vitamin K helps maintain bone health.†

No Artificial Flavors
No Preservatives
No Yeast or Gluten

Suggested Use: Take one tablet, two times per day with meal

Supplement Facts

Serving Size 1 tablet

	Per Tablet		Per Day (2 tablets)	
	Amount	%Daily Value	Amount	%Daily Value
Vitamin D	500 IU	125%	1000 IU	250%
Vitamin K	40 mcg	50%	80 mcg	100%
Calcium (USP)	500 mg	50%	1000 mg	100%

Ingredients: Calcium Carbonate, Maltodextrin, Polyvinyl Alcohol-Polyethylene Glycol Copolymer, Croscarmellose Sodium, Acacia, Titanium Dioxide (Artifical Color), Kaolin, Magnesium Stearate, Silicon Dioxide, Copovidone, Sodium Lauryl Sulfate, Corn Starch, Phylloquinone, Vitamin D3 (Cholecalciferol)

Expiration Date: June 2016 / Lot No. 1234-5678

†These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Manufactured and Distributed by:
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Council for Responsible Nutrition®
The Science Behind the Supplements®

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