How Dietary Supplements Are Regulated By The Federal Government

1. Dietary Supplements must be manufactured under the current Good Manufacturing Practices (DSHEA Section 9).
2. Accurate disclosure of contents is required (Fair Packaging & Labeling Act).
3. The label must state that the product is a “Dietary Supplement” (DSHEA Sec. 7 (a)).
4. 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.
5. Labeling must bear a phone number or address through which consumers can report serious adverse events (Dietary Supplement and Nonprescription Drug Consumer Protection Act).
6. Supplement manufacturers must register each facility with FDA (Bioterrorism Act).
7. Labels bearing statements of nutritional support must prominently display a prescribed advisory statement (DSHEA Section 6).
8. Lot number control is required to enable ingredient and product traceability during manufacture and Nature Made has chosen to put this number on its labels (Dietary Supplement Good Manufacturing Practices).
9. Disclosure of key allergens is required (Food Allergen Labeling Act).
10. Safety data regarding any “new dietary ingredients” must be submitted to FDA for non-food ingredients at least 75 days prior to marketing (DSHEA Section 8).
11. All ingredients must be safe for consumption (DSHEA Section 4 and Food Additive Regulations).
12. 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).
13. False or misleading claims are prohibited (FFDCA Section 403).
14. 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 must notify FDA of any such statements within 30 days of first marketing (DSHEA Section 6).
15. Health claims must be pre-approved by FDA (NLEA).
16. Labeling must bear a Supplement Facts table, including the name and quantity of each dietary ingredient (DSHEA Section 7).

Laws that Directly Impact Dietary Supplements