

# Overview: Dietary Supplement Labeling Regulations

Dietary supplements are required by federal regulations to have certain information on the label.

The below sample label with corresponding numbered explanations provides an overview of key labeling requirements.

1. Health claims must be approved by FDA and are subject to significant scientific agreement (21 CFR 101.14(c)).
2. Labeling must include a Supplement Facts panel that identifies the name and quantity of each dietary ingredient in the product (21 CFR 101.36).
3. Labeling may bear statements of nutritional support. The manufacturer must have substantiation that such statements are truthful and not misleading and notify FDA of these statements within 30 days of first marketing (21 USC 343(r)(6)(B) and (C)).
4. All ingredients must be safe for consumption (21 USC 342(f)(1)).
5. Dietary supplements may only be intended for oral ingestion (21 USC 321(ff)(2)(A)).
6. Labeling must bear a phone number or address through which consumers can report adverse events (21 USC 343(y)).
7. Each lot of dietary supplement is assigned a unique identifier to enable product traceability. A lot number is an example of a unique identifier (21 CFR 111.160(d)).
8. Although an expiration date is not required on the label, if provided, it should be supported by data (21 CFR 111 preamble).
9. The label must state the product is a "dietary supplement." The word "dietary" may be replaced with a description or name of the dietary ingredient(s) in the product (21 USC 343(s)(2)(B)).
10. Labels must contain an accurate statement of the quantity of the contents in terms of weight, measure or numerical count (21 USC 343(e)(2)).
11. Labels bearing statements of nutritional support must prominently display a prescribed disclaimer (21 USC 343(r)(6)(C)).

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

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## Supplement Facts

Serving Size 1 Tablet

|           | Amount Per Tablet | % Daily Value |
|-----------|-------------------|---------------|
| Vitamin D | 21 mcg            | 105%          |
| Calcium   | 650 mg            | 50%           |
| Magnesium | 63 mg             | 15%           |
| Zinc      | 2 mg              | 18%           |

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Ingredients: Calcium carbonate, magnesium oxide, maltodextrin, zinc oxide, cholecalciferol (vitamin D3).

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Suggested Use: Take 1 tablet daily with a meal.

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DISTRIBUTED BY:  
A Nutritional Product Company  
City, State, ZIP Code, Country, Phone number

7

LOT NO. 1234-5678

8

Expiration date: June 2020

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<sup>†</sup>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.

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— SAMPLE BRAND —  
Supports Strong Bones<sup>†</sup>

# CALCIUM Plus

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DIETARY SUPPLEMENT

10

100 Tablets



**Council for Responsible Nutrition**  
*The Science Behind the Supplements*

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