

# Dietary Supplements:

## What Physicians

## Should Know



Your patients may take dietary supplements, whether recommended by you or on their own, for a variety of reasons. Some supplements can help your patients meet the daily requirements of essential nutrients or can help improve or maintain their overall health. **But dietary supplements may also come with health risks that your patients should know about.**

### What is a Dietary Supplement?

**A dietary supplement is a product that is ingested and is intended to add to or “supplement” the diet.** A dietary supplement is not intended to be a substitute for conventional food or meals. Conventional food should always be the primary source of nutrients.

Dietary supplements can contain ingredients such as:

- Vitamins
- Minerals
- Herbs
- Botanical extracts and constituents
- Amino acids
- Enzymes
- Live microbials (commonly referred to as “probiotics”)

Dietary supplements come in a variety of forms such as tablets, capsules, softgels, gel caps, liquids, gummies, powders, and bars.

### How are Dietary Supplements Regulated?

Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the manufacturers and marketers of dietary supplements are responsible for ensuring that the products they sell are safe and lawful.



**Unlike FDA’s role in regulating prescription drugs, FDA does not have the authority to approve dietary supplements (for safety or efficacy) or their labeling before they are sold to the public.** In fact, companies can often introduce new dietary supplements to the market without even notifying FDA.



## What is FDA's Role?

**FDA's role in regulating dietary supplements primarily begins after products enter the marketplace.** FDA inspects manufacturing facilities for product quality and labeling (including claims) and monitors adverse event reports and product complaints to identify products that may be potentially unsafe. If a product is found to be unsafe or not otherwise in compliance with the law, FDA can work with the manufacturer to bring the product into compliance or possibly remove it from the market.

## How are Dietary Supplements Labeled?

Companies that manufacture or market dietary supplements are responsible for ensuring that product labels are truthful and not misleading.

FDA requires that certain information appear on supplement labels, including a statement on the front of the product identifying it as a "dietary supplement" or similar (e.g., "vitamin supplement").

**Dietary supplements are also required to have a Supplement Facts label that lists:**

- The serving size
- The number of servings per container
- Each dietary ingredient in the product
- The amount of certain ingredients (in milligrams or micrograms and the % Daily Value) per serving
- Information about dietary ingredients contained within proprietary blends
- Other ingredients (such as fillers, binders, preservatives, sweeteners, and flavorings) in descending order by weight

## What Claims are Permitted?

Products intended to treat, diagnose, prevent, mitigate, or cure diseases are drugs—and are subject to all requirements that apply to drugs—even if they are marketed as dietary supplements.

**Federal law permits dietary supplement manufacturers and marketers to make certain claims that describe how the product affects either the structure or the function of the human body if they can substantiate that the claims are truthful and not misleading.**

If the manufacturer chooses to make statements about the effects of the product on the structure or function of the human body, the manufacturer must also include a disclaimer on the product labeling that reads: "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."

<b>Supplement Facts</b>		
Serving Size 1 Gelcap Servings Per Container 100		
	<b>Amount Per Serving</b>	<b>% Daily Value</b>
Vitamin A (as retinyl acetate and 50% as beta-carotene)	900 mcg	100%
Vitamin C (as ascorbic acid)	90 mg	100%
Vitamin D (as cholecalciferol)	20 mcg (800 IU)	100%
Vitamin E (as dl-alpha tocopheryl acetate)	15 mg	100%
Thiamin (as thiamin mononitrate)	1.2 mg	100%
Riboflavin	1.3 mg	100%
Niacin (as niacinamide)	16 mg	100%
Vitamin B <sub>6</sub> (as pyridoxine hydrochloride)	1.7 mg	100%
Folate	400 mcg DFE (240 mcg folic acid)	100%
Vitamin B <sub>12</sub> (as cyanocobalamin)	2.4 mcg	100%
Biotin	3 mcg	10%
Pantothenic Acid (as calcium pantothenate)	5 mg	100%

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C Yellow No. 6, propylene glycol, preservatives (propylparaben and sodium benzoate).



## What are the Risks of Taking Dietary Supplements?

Dietary supplements may contain ingredients that can have strong effects in the body. Patients may experience harmful and even life-threatening consequences, especially if they:

- Use supplements with prescription or over-the-counter medications
- Take supplements instead of medications
- Combine supplements
- Consume supplements in high doses
- Take certain supplements when having lab work or surgery



## Did You Know?

**Products falsely marketed as dietary supplements can sometimes contain hidden pharmaceutical ingredients.** These are among the most concerning products sold as dietary supplements. Common hidden drug ingredients include sibutramine, sildenafil, tadalafil, and phenolphthalein.

## What is Your Role?

FDA strongly encourages you to talk to your patients about dietary supplements during your review of their medical health history.

- Ask your patients about what supplements they are taking, including how much, how often, and why.
- Counsel your patients about the benefits and risks of taking dietary supplements.
- Remind them to contact you before taking any supplement and especially if they experience any adverse reactions.

## Report Adverse Events to FDA

If you suspect that a dietary supplement may have caused your patient to experience an adverse event (such as a bad reaction, side effect, unexpected symptom, or illness), first tell your patient to immediately stop using the product. **You or your patient should then notify FDA by submitting a report through the Safety Reporting Portal at [www.safetyreporting.hhs.gov](http://www.safetyreporting.hhs.gov).**

This information is crucial to help FDA better protect the public from unsafe products.

Learn more about dietary supplements and get more detailed information that is important for the health and safety of your patients at [www.fda.gov/dietarysupplements](http://www.fda.gov/dietarysupplements).