



Strengthening Knowledge and Understanding of Dietary Supplements

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# Dietary Supplements

Background Information

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## What is a dietary supplement?

As defined by Congress in the [Dietary Supplement Health and Education Act](#), which became law in 1994, a [dietary supplement](#) is a product (other than tobacco) that

- is intended to supplement the diet;
- contains one or more dietary ingredients (including [vitamins](#); [minerals](#); [herbs](#) or other [botanicals](#); [amino acids](#); and other substances) or their [constituents](#);
- is intended to be taken by mouth as a pill, [capsule](#), tablet, or liquid; and
- is [labeled](#) on the front panel as being a dietary supplement.



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## What is a new dietary ingredient?

A *new dietary ingredient* is a dietary ingredient that was not sold in the United States in a dietary supplement before October 15, 1994. The [U.S. Food and Drug Administration](#) (FDA) requires [specific safety information](#) from a manufacturer intending to market a dietary supplement containing a new dietary ingredient. This information is not required for older dietary supplement ingredients.

## Are dietary supplements different from foods and drugs?

Although dietary supplements are [regulated](#) by the FDA as foods, they are regulated differently from other foods and from [drugs](#). Whether a product is classified as a dietary supplement, [conventional food](#), or drug is based on its intended use. Most often, classification as a dietary supplement is determined by the information that the manufacturer provides on the product label or in accompanying literature, although many food and dietary supplement product labels do not include this information.

## What claims can manufacturers make for dietary supplements and drugs?

The types of claims that can be made on the labels of dietary supplements and drugs differ. Drug manufacturers may claim that their product will [diagnose](#), [cure](#), [mitigate](#), [treat](#), or [prevent](#) a disease. Such claims may not legally be made for dietary supplements.

The label of a dietary supplement or food product may contain one of [three types of claims](#): a [health claim](#), [nutrient content claim](#), or [structure/function claim](#). Health claims describe a relationship between a food, food component, or dietary supplement ingredient, and reducing [risk](#) of a disease or health-related condition. Nutrient content claims describe the relative amount of a [nutrient](#) or dietary substance in a product. A structure/function claim is a statement describing how a product may affect the organs or systems of the body and it can not mention any specific disease. Structure/function claims do not require FDA approval but the manufacturer must provide FDA with the text of the claim [within 30 days of putting the product on the market](#). Product labels containing such claims must also include a disclaimer that reads, "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease."

## How does FDA regulate dietary supplements?

In addition to regulating label claims, FDA regulates dietary supplements in other ways. [Supplement](#) ingredients sold in the United States before October 15, 1994, are not required to be reviewed by FDA for their safety before they are marketed because they are presumed to be safe based on their history of use by humans. For a new dietary ingredient (one not sold as a dietary supplement before 1994) the manufacturer must notify FDA of its intent to market a dietary supplement containing the new dietary ingredient and provide information on how it determined that reasonable [evidence](#) exists for safe human use of the product. FDA can either refuse to allow new ingredients into or remove existing ingredients from the marketplace for safety reasons.

Unlike drug products, there are no provisions in the law for FDA to "approve" dietary supplements for safety or effectiveness before they reach the consumer. Once a dietary supplement is marketed, FDA has to prove that the product is not safe in order to restrict its use or remove it from the market. In contrast, before being allowed to market a drug product, manufacturers must obtain FDA approval by providing convincing evidence that it is both safe and effective.

The label of a dietary supplement product is required to be truthful and not misleading. If the label does not meet this requirement, FDA may remove the product from the marketplace or take other appropriate actions.

## What information is required on a dietary supplement label?

FDA requires that certain information appear on the dietary supplement label:

### General information

- Name of product (including the word "supplement" or a statement that the product is a supplement)
- Net quantity of contents
- Name and place of business of manufacturer, packer, or distributor
- Directions for use

### Supplement Facts panel

- Serving size, list of dietary ingredients, amount per serving size (by weight), percent of [Daily Value](#) (%DV), if established
- If the dietary ingredient is a botanical, the scientific name of the plant or the common or usual name standardized in the reference *Herbs of Commerce* (1992 edition) and the name of the plant part used
- If the dietary ingredient is a [proprietary](#) blend (i.e., a blend exclusive to the manufacturer), the total weight of the blend and the components of the blend in order of predominance by weight

## Other ingredients

- Nondietary ingredients such as [fillers](#), artificial colors, sweeteners, flavors, or [binders](#); listed by weight in descending order of predominance and by common name or proprietary blend

The label of the supplement may contain a cautionary statement but the lack of a cautionary statement does not mean that no [adverse effects](#) are associated with the product.

## Does a label indicate the quality of a dietary supplement product?

It is difficult to determine the quality of a dietary supplement product from its label. The degree of [quality control](#) depends on the manufacturer, the supplier, and others in the production process.

In 2007, the FDA issued Good Manufacturing Practices (GMPs) for dietary supplements, a set of requirements and expectations by which dietary supplements must be manufactured, prepared, and stored to ensure quality. Manufacturers are now expected to guarantee the identity, purity, strength, and composition of their dietary supplements. For example, the GMPs aim to prevent the inclusion of the wrong ingredients, the addition of too much or too little of a dietary ingredient, the possibility of contamination (by pesticides, heavy metals such as lead, bacteria, etc.), and the improper packaging and labeling of a product.

## Are dietary supplements standardized?

[Standardization](#) is a process that manufacturers may use to ensure batch-to-batch consistency of their products. In some cases, standardization involves identifying specific chemicals (known as markers) that can be used to manufacture a consistent product. The standardization process can also provide a measure of quality control.

Dietary supplements are not required to be standardized in the United States. In fact, no legal or regulatory definition exists in the United States for standardization as it applies to dietary supplements. Because of this, the term "standardization" may mean many different things. Some manufacturers use the term standardization incorrectly to refer to [uniform](#) manufacturing practices; following a recipe is not sufficient for a product to be called standardized. Therefore, the presence of the word "standardized" on a supplement label does not necessarily indicate product quality.

## What methods are used to evaluate the health benefits and safety of a dietary supplement?

Dietary supplements are not required by federal law to be tested for safety and effectiveness before they are marketed, so the amount of scientific evidence available for various supplement ingredients varies widely. Some ingredients in dietary supplements have been carefully evaluated. For example, scientists know that calcium and vitamin D are important for keeping bones strong and reducing bone loss. Other supplements, such as many herbal products, need more study to determine their value.

Scientists can use several approaches to evaluate dietary supplements for their potential health benefits and risks. They may investigate history of use, conduct [laboratory studies](#) using [cell](#) or tissue cultures, and experiment with animals. Studies on people (e.g., individual [case reports](#), observational studies, and [clinical trials](#)) provide the most direct evidence of a dietary supplement's effects on health and patterns of use.

## What are some additional sources of information on dietary supplements?

Medical libraries are one source of information about dietary supplements. Others include Web-based resources such as [PubMed](#) and [FDA](#) [🔗](#). For general information on botanicals and their use as dietary supplements please see [Background Information About Botanical Dietary Supplements](#).

## Disclaimer

This fact sheet by the Office of Dietary Supplements provides information that should not take the place of medical advice. We encourage you to talk to your healthcare providers (doctor, registered dietitian, pharmacist, etc.) about your interest in, questions about, or use of dietary supplements and what may be best for your overall health. Any mention in this publication of a specific brand name is not an endorsement of the product.