

Dietary Supplements: What Are They?

What is a dietary supplement?

A dietary supplement is intended to supplement the diet with one or more dietary ingredients such as vitamins, minerals, herbs, or amino acids. It is labeled on the front panel as being a dietary supplement.

Does the Food and Drug Administration (FDA) regulate dietary supplements?

No, the FDA is not authorized to review dietary supplement products for safety and effectiveness before they are marketed. After a dietary supplement is marketed, manufacturers must report serious problems to the FDA within 15 days of learning of a problem. The FDA has to prove that a product is not safe in order to restrict its use or take it off the market.

Supplement ingredients that have been sold in the United States since before October 15, 1994 are assumed safe for human use. If a manufacturer wants to include a new ingredient it must notify the FDA and provide reasonable evidence that it is safe for human use. The FDA can refuse to allow a new ingredient.

The label of a dietary supplement is required to be truthful and not misleading. If the label does not meet this requirement, the FDA may remove the product from the market.

How are dietary supplements manufactured?

Since June 2010, dietary supplement manufacturers and distributors in the United States are required to manufacture, label, document, and store products in compliance with current Good Manufacturing Practices (cGMP). These practices include:

- Manufacturing facility is in good condition and is clean and sanitary
- Equipment is properly maintained and calibrated

- Employees are qualified and fully trained
- Production system includes quality control for manufacturing, packaging, labeling, and storage.

How do I know if a company is following Good Manufacturing Practices?

There is no easy way to know. Some companies put a logo on their product label or website such as “Certified GMP” or “FDA Approved Facility”. These are not official and misuse of the FDA logo is illegal.

The FDA inspects manufacturers once every 3 to 7 years to assess compliance to cGMP. This is not a certification or approval process. The goal is to alert manufacturers of violations so they can be corrected. In 2019, 598 dietary supplement manufacturers were inspected. A little over half were found to have violations. The most common violations were failure to:

- Establish specifications for the identity, purity, strength, and composition of the finished supplement
- Establish or follow written procedures for quality control.

For more information, go to <https://tinyurl.com/yccxsvkp>

How can I be a smart supplement shopper?

It is common for people to think that if something is natural it is also safe. However, natural plant-based supplements contain powerful active ingredients that may cause harm. They can:

- Cause side effects, especially if taken in high doses
- Increase the risk of bleeding or interact with anesthesia and need to be stopped before surgery
- Interact with other supplements or medications to make them more or less effective
- Worsen disease.

Protect yourself by researching the potential benefit and harm associated with using a supplement. Avoid getting your information from the manufacturer. Instead use non-commercial internet sites such as:

- American Society of Anesthesiologists - Herbal and Dietary Supplements and Anesthesia: <https://tinyurl.com/y92ptxgf>
- FDA - Information for Consumers on Using Dietary Supplements: <https://tinyurl.com/ybogifpz>
- MedlinePlus - Drugs, Herbs and Supplements: <https://tinyurl.com/y4euh8pn>
- National Center for Complementary and Integrative Health - Know the Science: How Medications and Supplements Can Interact <https://tinyurl.com/ycyfgpxr>
- National Institute of Health (NIH) Office of Dietary Supplements - Dietary Supplements: What You Need to Know: <https://tinyurl.com/ma3f8v6>

How can I report a problem to the FDA?

The FDA relies on consumers to report problems. If you think taking a supplement has caused a bad effect, or have other concerns, report the problem by:

- Contacting the FDA Consumer Complaint Coordinator for your state: <https://tinyurl.com/yce8yaqp>
- Filing a safety report online through the Safety Reporting Portal: <https://tinyurl.com/yc9nkb8d>
- For more information on reporting visit the FDA's reporting webpage: <https://tinyurl.com/y9tm8kx8>

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