

Information for Consumers on Using Dietary Supplements

Who is Responsible for Ensuring the Safety and Efficacy of Dietary Supplements?

Unlike prescription and over-the-counter medicines, dietary supplement products are not reviewed by the government before they are marketed. Companies and individuals who manufacture or market dietary supplements are responsible for ensuring that their products are safe and lawful. Firms can introduce new dietary supplement products to the market without receiving approval from the FDA. In fact, firms can often lawfully introduce dietary supplements to the market without even notifying the FDA.

What is FDA's Responsibility in Regulating Dietary Supplements?

The FDA has the responsibility to take action against unsafe dietary supplement products, including those marketed for personalized nutrition, after they reach the market. The FDA's role in regulating dietary supplements includes inspecting manufacturing establishments for product quality, labeling, and claims as well as monitoring adverse event reports from firms, consumers, and health care professionals to identify products that may be unsafe.

What If I Think I Have Had A Reaction to A Dietary Supplement?

If you experience an adverse event while taking a dietary supplement, stop consuming the product, seek immediate medical care or advice, and report the adverse event to the FDA through the [Safety Reporting Portal \(http://www.safetyreporting.hhs.gov\)](http://www.safetyreporting.hhs.gov).

Please be aware that you can experience serious health-related reactions or illnesses (known as adverse events) with the use of dietary supplement products. The FDA does not approve dietary supplements for safety and effectiveness before they are sold to the public, so it is particularly important for consumers, health care professionals, and industry members to report these incidences to the FDA so that the Agency can take action to protect the public from unsafe products.

What's the Bottom Line?

- Dietary supplements are intended to supplement the diet, not to cure, prevent, or treat diseases or replace the variety of foods important to a healthful diet.
- Supplements can help you meet daily requirements for certain nutrients, but when you combine drugs and foods, too much of some nutrients can also cause problems.
- Many factors play a role in deciding if a supplement is right for you, including possible drug interactions and side effects.
- Do not self-diagnose any health condition. Together, you and your healthcare team can make the best decision for optimal health.

Learn more at:

U.S. Food and Drug Administration, Office of Dietary Supplement Programs:
<https://www.fda.gov/food/dietary-supplements>