Understanding Dietary Supplements

You've probably heard about dietary supplements and may even take them regularly. You may have also recommended them to friends or family. While supplements can be beneficial to your health, they can also involve health risks. Before making decisions about whether to take a supplement, it is important to talk to your healthcare provider. And, since the FDA does not have the authority to approve or in many cases even review supplements before they are sold to consumers, it is important that you report any adverse events (i.e., side effects or bad reactions) you may experience to FDA.

Dietary Supplements at a Glance

Dietary supplements are products intended to add to, or "supplement," your diet. Common dietary supplements include:

- Vitamins, either as individual or multivitamins, such as vitamin C, vitamin D, vitamin B12, and biotin (B7)
- Minerals, such as calcium and iron
- Botanicals or herbals, like chamomile or ginger, as well as extracts and compounds from botanicals, like caffeine or curcumin
- Amino acids, such as tryptophan and glutamine
- Probiotics
- Protein

Dietary supplements come in many forms such as pills, tablets, powders, liquids, and energy bars. Sometimes it can be tricky to determine whether a product is a food or a dietary supplement. Packaged foods have a "Nutrition Facts" panel on their labels, while dietary supplements have a "Supplement Facts" panel. Reading the panel can help you recognize the product type and understand what nutrients it contains.

Benefits of Dietary Supplements

Dietary supplements can improve overall health and can help you meet the daily requirements of essential nutrients that your body needs to function. Even though dietary supplements can be helpful and beneficial, there can be risks associated with these products. They also should not take the place of the variety of foods that are important for a healthy diet. To get the most out of dietary supplements and make sure they are working for you, talk to your healthcare provider.

Risks and Adverse Events

Many supplements contain ingredients that can have strong effects in the body. And the safety of supplements is not guaranteed. Dietary supplements should not be taken instead of prescribed medications. You may have side effects, bad reactions, or even illness if you take too much of one supplement, combine supplements, or use supplements with over-the-counter or prescription medicines, including birth control.

Always be alert to the possibility of a reaction, especially when taking a new product. These bad reactions are known as adverse events and can include, but are not limited to:

- Itching
- Fatigue
- Slurred speech
- Blood in urine
- Diarrhea
- Severe joint and muscle pain
- Heart palpitations

For a full list of reactions please see https://www.fda.gov/food/dietary-supplements/how-report-problem-dietary-supplements.

If you think that a dietary supplement may have caused an adverse event, you should immediately stop using the product and seek medical care or advice. You should also submit a report to FDA through the Safety Reporting Portal at https://www.safetyreporting.hhs.gov or by calling a Consumer Complaint Coordinator. The phone number for the Consumer Complaint Coordinator assigned to your state can be found at https://www.fda.gov/safety/report-problem-fda/consumer-complaint-coordinators. Any information a consumer can provide will help FDA identify problematic products on the market and enable the agency to take action, which will protect you and others from unsafe products.

Before Taking a Supplement

Before taking dietary supplements, ask yourself these questions:

- Is taking this dietary supplement an important part of my overall health?
- Am I taking the right product?
- Am I taking the right amount?
- Is it safe to combine this supplement with any other supplements or medications I am taking?

To answer these questions and avoid adverse events, talk to your healthcare provider. They can determine which supplements you should take, how much you should take, and how long to take them.

Did You Know?

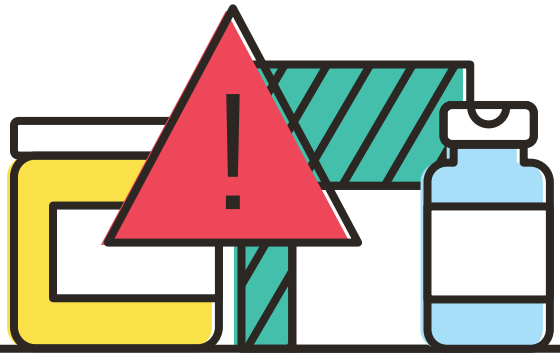
Under the Dietary Supplement Health and Education Act (DSHEA), the FDA does not have the authority to approve dietary supplements. In fact, companies can often introduce a dietary supplement to the market without even notifying the FDA. The companies are responsible for ensuring that their dietary supplements are safe and lawful before they go to market. If they are not safe or lawful, FDA can take action after they reach the market. That's why reporting adverse events and side effects through the Safety Reporting Portal is important.

Dietary Supplements and Adverse Events

What is an adverse event?

It is possible to experience an adverse event, also known as a side effect or bad reaction, while using dietary supplements. Sometimes these reactions can be life-threatening. Examples include:

- Itching, rash, hives, throat/lip/tongue swelling, wheezing
- Low blood pressure, fainting, chest pain, shortness of breath, palpitations, irregular heartbeat
- Severe, persistent nausea, vomiting, diarrhea, or abdominal pain
- Difficulty urinating, decreased urination
- Fatigue, appetite loss, yellowing skin/eyes, itching, dark urine
- Severe joint/muscle pain
- Slurred speech, one-sided weakness of face, arm, leg, vision (stroke)
- Abnormal bleeding from nose or gums
- Blood in urine, stool, vomit, or sputum
- Marked mood, cognitive, or behavioral changes, thoughts of suicide
- Visit to Emergency Room or hospitalization



What should I do if I experience an adverse event?

If you are taking a dietary supplement and experience an adverse event, you should immediately stop using the product and seek immediate medical care or advice. You should also submit a report to FDA through the Safety Reporting Portal at https://www.safetyreporting.hhs.gov or by calling a Consumer Complaint Coordinator. The phone number for the Consumer Complaint Coordinator assigned to your state can be found at https://www.fda.gov/safety/report-problem-fda/consumer-complaint-coordinators. Please provide as much information as you can. Complete reports are the most useful, but even pieces of information can help protect the public from potentially unsafe products.

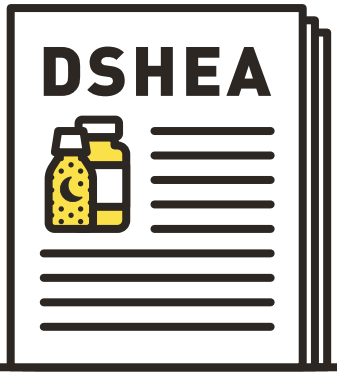
Even if you aren't sure the supplement caused the adverse event, it's always better to report it.

Why should I report an adverse event?

By law, FDA does not have the authority to approve dietary supplements before they are sold to the public; in fact, in most cases, FDA isn't even notified of a new dietary supplement. When you report an adverse event or make a complaint, FDA is able to identify potentially dangerous products and possibly remove them from the market. To see the latest actions FDA has taken to protect the public health, visit https://www.fda.gov/food/dietary-supplements/whats-new-dietary-supplements.

Dietary Supplements: How FDA Keeps You Safe

Dietary supplements are regulated as a category of foods.

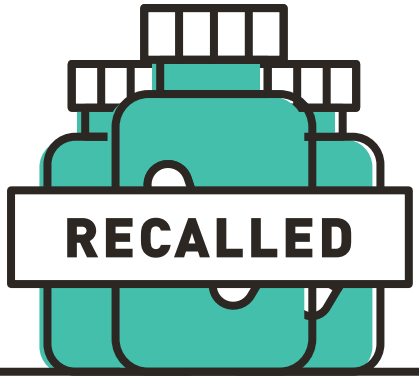


In 1994, the Dietary Supplement Health and Education Act (DSHEA) was enacted into law. It defined dietary supplements and set out FDA's authority regarding these products. Dietary supplements are a category of foods and, therefore, FDA does not have the authority to approve dietary supplements or their labeling before products are sold in stores or online. In fact, companies can often lawfully produce and market a new dietary supplement without even notifying FDA. Dietary supplement companies are responsible for ensuring that their products are safe and label claims are truthful.

FDA regulates.

Even though FDA does not approve dietary supplements, there are product manufacturing and labeling requirements in place that supplement companies are required to follow. For example, if a supplement claims to promote health or support a body function, like immunity or heart health, it must also say: "This statement has not been evaluated by the Food and Drug Administration." FDA periodically inspects manufacturing facilities to verify companies are meeting the requirements for product quality, labeling, and claims. The agency also monitors reports and complaints received from consumers, healthcare professionals, and industry.

FDA takes action.



When products are found to be out of compliance with FDA requirements or potentially unsafe, FDA is responsible for taking action. In these cases, FDA can work with the manufacturer to bring the product into compliance or, if needed, the agency has the authority to remove unsafe or misbranded products from the market or ask the manufacturer to voluntarily recall the product. To see the latest actions FDA has taken to protect the public health, visit https://www.fda.gov/food/dietary-supplements/whats-new-dietary-supplements.