

# Dietary Supplements:

# Report Adverse Events to FDA

Dietary supplements can be beneficial to your health, but they can also have unexpected consequences, especially if you start taking a new product, take supplements in high doses, take multiple supplements, or take supplements instead of or in addition to medications.



**Before deciding to take a dietary supplement, always talk to your healthcare professional.**

## 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. Adverse events may occur immediately or can happen sometime later and can range from less serious reactions to life-threatening illnesses, such as:

- Itching, rash, hives, or wheezing
- Fatigue or appetite loss
- Severe, persistent nausea, vomiting, diarrhea, or abdominal pain
- Difficulty urinating, decreased urination, or dark urine
- Marked mood, cognitive, or behavioral changes
- Severe joint or muscle pain
- Yellowing of the skin or eyes
- Abnormal bleeding from the nose or gums
- Blood in urine, stool, or vomit
- Throat, lip, or tongue swelling
- Low blood pressure, fainting, chest pain, or shortness of breath
- Stroke (slurred speech, one-sided weakness of face, arm, leg, or blurry/loss of vision)

## What Should I Do if I Experience an Adverse Event?

If you are taking a dietary supplement and experience an adverse event, immediately stop using the product and seek medical care or advice.

You should also submit a report to FDA through either:

- The **Safety Reporting Portal** at [www.safetyreporting.hhs.gov](http://www.safetyreporting.hhs.gov).
- An **FDA Consumer Complaint Coordinator**. You can find the phone number for your local Consumer Complaint Coordinator at [www.fda.gov/consumer-complaint-coordinators](http://www.fda.gov/consumer-complaint-coordinators) or by calling FDA's SAFEFood Information Line at 1-888-SAFEFood (1-888-723-3366).

Even if you aren't sure the dietary supplement caused the adverse event, it's always better to report it to FDA. Try to **provide as much information as possible**. Complete reports are the most useful, but even pieces of information can be helpful.



## Experiencing an Adverse Event?

- 1: **STOP** taking the supplement immediately
- 2: **SEEK** medical care
- 3: **REPORT** the adverse event to FDA

## 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 when a dietary supplement is introduced to the market. However, when you report an adverse event associated with a dietary supplement, FDA can use the information you provide to help identify potentially dangerous products and possibly remove them from the market.

**In some cases, a single adverse event report can be very helpful to FDA in investigating and taking action to protect other consumers from unsafe products.** That's why it's so important for you to notify FDA about any adverse reactions to a dietary supplement.

To learn about dietary supplement-related actions that FDA has taken to protect the public health, visit: [www.fda.gov/dietarysupplements](http://www.fda.gov/dietarysupplements).

