

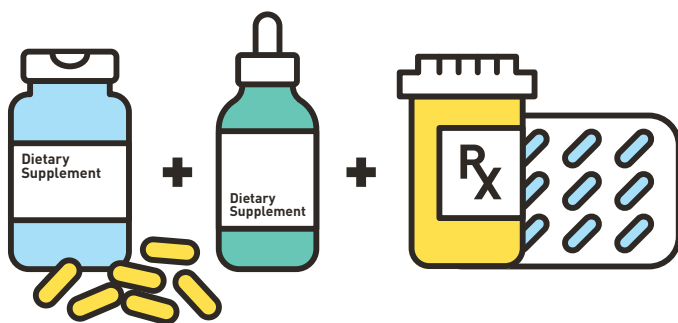
# Dietary Supplements and Adverse Events



## Recognizing Adverse Events

Dietary supplements may contain ingredients that can have strong effects in the body, so you and your patients should always be alert to the possibility of bad reactions, side effects, unexpected symptoms, or illnesses—also known as adverse events.

**Adverse events are more likely to occur when taking a new product, taking supplements in high doses, taking multiple supplements, or taking supplements instead of or in addition to medications.**



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

Bad reactions can even result in Emergency Room visits or hospitalization.



## Reporting Adverse Events to FDA

**You play a crucial public health role by reporting adverse events to FDA.** By reporting a reaction to a dietary supplement, or even the suspicion of a problem, you can help FDA protect the public from potentially unsafe products.

If you believe that a dietary supplement may be causing your patient to experience an adverse event, first tell your patient to stop using the product and seek immediate medical care. You or your patient should then **notify FDA by submitting a report through the Safety Reporting Portal at [www.safetyreporting.hhs.gov](http://www.safetyreporting.hhs.gov).**

Collect and provide as much information as possible about the patient, the product, and the problem. Complete reports are the most useful, but even pieces of information can be helpful.

## Reporting is Important

**By law, FDA does not have the authority to approve dietary supplements (for safety or efficacy) or their labeling before they are sold to the public.** In fact, companies can often introduce new dietary supplements to the market without even notifying FDA.

Therefore, it is particularly important for you to report adverse events. **This information helps FDA evaluate the safety of marketed products, 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 public health.

