

Reporting Adverse Events Associated with Dietary Supplement Use

What is an adverse event?

“Adverse events” (side effects) are unfavorable or unusual reactions, effects, or illnesses that can occur with the use of some dietary supplements, just as they can with over-the-counter and prescription medications. Adverse events can be mild to serious. Examples of adverse events include nausea, vomiting, headaches, dizziness, jitteriness or shakiness, rapid or irregular heart rate, chest pain, shortness of breath, marked changes in mood or behavior, and yellowing of the skin or eyes (which could be an indicator of liver injury).

What should I do if I’ve experienced an adverse event?

If you experience ANY adverse event, stop taking the dietary supplement product, tell your healthcare provider, and report the event to the Food and Drug Administration (FDA).

Why is it important to report adverse events?

Reporting adverse events helps FDA identify and take action against any unsafe products on the market.

How do I report an adverse event?

To report an adverse event to FDA:

1. Visit OPSS.org and click on “Report Side Effects” or go directly to <https://www.safetyreporting.hhs.gov/>.
2. Begin by either creating an account or reporting as a guest.
3. Complete the form by filling in the required information and submit when done.