

FOR INDUSTRY

Dietary Supplements

Reporting an Adverse Event

At A Glance



The Requirement

Manufacturers, packers, and distributors of dietary supplements in the United States are required to report information about serious adverse effects associated with the use of these supplements to the Food and Drug Administration (FDA).

This requirement is detailed in the Dietary Supplement and Nonprescription Drug Consumer Protection Act, enacted on December 22, 2006. The effective date for complying with this requirement was December 22, 2007.

What Is a Dietary Supplement?

For the purposes of reporting an adverse event to the FDA, dietary supplements are products intended to supplement the diet and include one or more of the following ingredients:

- > Vitamins
- > Minerals
- > Herbs or other botanicals
- > Amino acids
- > Any dietary substance for use by man to supplement the diet by increasing total dietary intake or any concentrate, metabolite, constituent, or extract or any combination of any ingredient listed above.

Who Must Report

The manufacturer, packer, or distributor of a dietary supplement marketed in the United States whose name appears on the label of the supplement is required to report serious adverse events.

According to the law, a dietary supplement label must include contact information (the domestic address or phone number) for the supplement's manufacturer, packer, or distributor. The law refers to this entity as the "responsible person."

What Events Must Be Reported

The "responsible person" must report any serious adverse event associated with the use of dietary supplements.

An adverse event is "any health-related event associated with the use of a dietary supplement that is adverse." A serious adverse event is an adverse event that:

- > Results in:
 - Death
 - A life-threatening experience
 - Inpatient hospitalization
 - A persistent or significant disability or incapacity
 - A congenital anomaly or birth defect; or



- › Requires, based on a reasonable medical judgment, a medical or surgical intervention to prevent an outcome described above.

FDA is authorized to have access to all adverse event report records that dietary supplement manufacturers, packers, and distributors are required to maintain.

How to Submit an Adverse Event Report

To submit a serious adverse event report for a dietary supplement:

1. Go to **Reporting Serious Problems to the FDA: Download Forms**.
2. Click **Form FDA 3500A – Mandatory Reporting**.
3. Complete the following sections of MedWatch Form FDA 3500A:
 - Patient Information (Section A):
 - Adverse Event or Product Problems (Section B): Note that blocks 5 and 6 are not required for reports on dietary supplements.
 - Suspect Product (Section C)
 - Initial Reporter (Section E)
 - All Manufacturers (Section G)
4. Obtain a copy of the label of the dietary supplement.
5. Mail the form along with the product label to this address:

U.S. Food and Drug Administration
CAERS Team HFS-11
5100 Paint Branch Parkway
College Park, MD 20740

Note: Reports may not be submitted electronically or by fax.

Send follow-up reports with additional medical information to this same address.

For more information on completing the form, see *Instructions for Completing the MedWatch Form 3500A to Report a Serious Adverse Event Associated with a Dietary Supplement*.

When to Submit Reports

The following must be submitted to FDA **no later than 15 business days** after the report is received by the “responsible person”:

- › Any serious adverse event report
- › All follow-up reports of new medical information.

Report Submission Is Not an Admission of Fault

Submitting a serious adverse event report will not be construed by FDA as an admission that the dietary supplement involved caused or contributed to the adverse event being reported, or that any person included in the report caused or contributed to the event.

How Long Must Adverse Event Reports Be Kept?

Adverse event reports and related records must be maintained for a period of 6 years. For each serious adverse event this includes:

- › The original MedWatch Form FDA 3500A form submitted and any attachments
- › Any related medical information received after submitting the initial report
- › Any reports submitted to FDA including new medical information
- › Communications between the “responsible person” and the initial reporter or any other person who provided information related to the adverse event.

For more information

On the *FDA.gov* website go to Food>Dietary Supplements>Guidance, Compliance, & Regulatory Information.

- The Law: Dietary Supplement and Nonprescription Drug Consumer Protection Act
- Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements
- Instructions: Completing the MedWatch Form 3500A to Report a Serious Adverse Event Associated with a Dietary Supplement

You may also email questions to CAERS@fda.hhs.gov.