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**Safety**

## How Consumers Can Report an Adverse Event or Serious Problem to FDA

[En Español](#)<sup>1</sup>

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by you health care provider, or your health care provider may choose not to complete the form. Your health care provider is NOT required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

### Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

1. [Report Online](#)<sup>2</sup>
2. [Consumer Reporting Form FDA 3500B](#)<sup>3</sup>. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see [MedWatchLearn](#)<sup>4</sup>.
3. **Call FDA at 1-800-FDA-1088** to report by telephone
4. [Reporting Form FDA 3500](#)<sup>5</sup> commonly used by health professionals. [View Instructions for Form FDA 3500](#)<sup>6</sup>

### Guides to Reporting Problems to FDA

- [MedWatchLearn](#)<sup>7</sup> - Teaching students, health professionals, and consumers how to report problems to FDA
- ["Kids Have Problem With Medical Product?"](#)<sup>8</sup> (Consumer Update, February 2013)
- [FDA 101: How to Use the Consumer Complaint System and MedWatch](#)<sup>9</sup> (June 10, 2008)
- [Your Guide to Reporting Problems to FDA](#)<sup>10</sup> (June 10, 2008)

### Related Information for Consumers

- [Report suspected unlawful sale of medical products on the Internet](#)<sup>11</sup>
- If you need information or if you have questions or comments about a medical product, please call the FDA's toll-free information line, **1-888-INFO-FDA (1-888-463-6332)** Press 2, followed by 1 for information, then:
  - for dietary supplements, select 2
  - for drug products, select 3

- for medical devices, select 4
- for biologics, including human cells, tissues, and cellular and tissue-based products, select 6

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Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

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U.S. Department of **Health & Human Services**

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