
FDA 101: How to Use the Consumer Complaint System and MedWatch

 

If you have a complaint about a product regulated by the Food and Drug Administration (FDA), the agency wants to hear about it.

FDA offers a number of ways to report a complaint. Two of the main reporting systems available to consumers are the Consumer Complaint Reporting system and MedWatch.

1. Consumer Complaint Reporting

FDA's Consumer Complaint Coordinators (CCC's) located in FDA offices throughout the United States and Puerto Rico will listen, document your complaint about an FDA-regulated product, and follow up as necessary. Consumers should report problems to the CCC for their geographic region. (See the list of CCC's on FDA's Web site at [Consumer Complaint Coordinators](#).)

Some examples of complaints that your CCC wants to hear about are

- food-related illnesses, especially when a specific food is suspected
- allergic reactions when a person has a known allergy to a food ingredient not identified on the product label

- problems related to infant formula
- problems related to baby food
- swollen or leaking canned goods
- suspected product tampering
- adverse events after taking dietary supplements
- problems related to prescription or over-the-counter medications
- problems related to pet food and treats

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Reporting Problems Can Spur Action

If a person reports an illness or injury that appears likely to be caused by an FDA-regulated product, FDA acts immediately. Depending on the seriousness of the problem, an FDA investigator may visit the person who made the complaint, collect product samples, and initiate inspections.

"Just a few complaints can make a difference," says Joan Trankle, FDA's National CCC. For example:

- CCC's in different parts of the country received three reports of allergic reactions to a type of soymilk. FDA followed up with an inspection of the soymilk company. The product did not declare the allergenic substance, milk protein, on the label, and the company recalled the product.
- CCC's received two complaints in one week about skin burns after use of an adhesive patch that generates heat to relieve muscle and joint pain. "When that second complaint arrived, we sprang into action," says Trankle. "We contacted the firm and, based on our follow-up, the firm recalled the product."

Complaints of a less serious nature, or those that appear to be isolated incidents, are monitored and the information is used during a future inspection of a company to help FDA identify problem areas in a production plant. The complaints are also discussed with company management during these inspections.

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2. MedWatch Reporting

MedWatch is for reporting any adverse events (unexpected side effects) that occur while using human health care products and some other FDA-regulated products such as

- human drugs (both prescription and over-the-counter)
- medical devices (for example, contact lenses, glucose tests, pacemakers, and medical x-rays)
- blood products, human cell and tissue products, and other biologics (except vaccines, which are reported to another system)
- special nutritional products (dietary supplements, infant formulas, and

- medical foods such as nutritional supplements used under medical supervision)
- cosmetics

When FDA approves a medical product, the agency has determined that the benefits of the product outweigh the risks. "But every product that FDA approves carries some risk," says Norman Marks, M.D., Medical Director of FDA's MedWatch Program. "Sometimes there are risks that only come to light after a medical product gets on the market and is used in a larger number of patients, for a longer period of time, and in patients whose health characteristics are different from those of the patients studied before approval." So continued monitoring of adverse events is essential and depends on reporting of these events to FDA so they can be entered in MedWatch.

Every MedWatch report is important and is recorded in an FDA database for review and comparison to similar previous reports. When added together, reports can signal a safety problem and lead to an FDA action to protect the public, says Marks. "Reporting can help you, a family member, or someone else avoid harm, serious illness, or even death."

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How to Report to MedWatch

Reporting to MedWatch is easy, confidential, and secure. You provide information about your experience on a MedWatch form. FDA encourages you to have your health care professional either complete the form for you or help you complete the form yourself. "Health care professionals have test results and other clinical information that will help us better evaluate the report," says Marks.

Reporting by health care professionals is voluntary. If they choose not to report, or if you'd rather file the report yourself, you may use one of these methods:

- **Online** - Use the interactive form at [FDA Form 3500](#). FDA encourages online reporting because it is the quickest and most direct route.
- **Mail** - Download the pre-addressed, postage-paid form ([FDA Form 3500](#)) or call 1-800-FDA-1088 to request the form.
- **Fax** - Get the form (as above) and fax to 1-800-FDA-0178.
- **Phone** - Call 1-800-FDA-1088 Mon–Fri between 8:00 a.m. and 4:30 p.m. EST.

If you or your health care professional does not want to complete a MedWatch report, you may report a problem with a health care product to your CCC. "There are times when consumers want to explain their problem and have us record the complaint," says Trankle. "This gives us the advantage of being able to ask questions and obtain important information that we might not get if they were filling out a MedWatch report."

CCC's and MedWatch are for reporting problems; neither provides medical advice. If you experience an adverse event, you should contact your health care professional first and then report the problem to FDA.

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What Happens After Reporting to MedWatch?

- FDA staff enter the report into a database so that it is available for review and comparison to other reports.
- An FDA safety evaluator, often a pharmacist, doctor, or nurse, reviews the report and examines the database for similar reports.
- FDA monitors the data for trends and conducts an investigation if appropriate.
- FDA takes necessary action to protect public health.

FDA actions may include

- issuing safety alerts advising the public and health care professionals to monitor a product's use, adjust the way it is used, or stop using it
- updating the product labeling to reflect new warnings
- requiring a product to have a Medication Guide—a consumer-friendly instruction sheet provided to patients each time they fill a prescription to help them use the drug safely
- requesting a change in the product's design, manufacturing process, packaging, or distribution
- requesting a company to recall a product or requiring a manufacturer to conduct further studies to demonstrate the product's safety prior to allowing the product back on the market

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Problems to Report to MedWatch MedWatch is for reporting four types of problems with human health care products. Examples of each are shown here.			
1. Serious adverse event	2. Product quality problem	3. Product use error	4. Problem with different manufacturer of same medicine
<ul style="list-style-type: none"> • death • life-threatening situation • requires admission to 	<ul style="list-style-type: none"> • suspected counterfeit product • potentially contaminated product 	<ul style="list-style-type: none"> • mixing up products with similar drug names or packaging 	<ul style="list-style-type: none"> • not getting same results from a generic

<p>hospital or longer-than-expected hospital stay</p> <ul style="list-style-type: none"> • permanent disability • birth defect, miscarriage, stillbirth, or birth with serious disease • requires medical care to prevent permanent damage 	<p>indicated by suspicious odor or unusual color</p> <ul style="list-style-type: none"> • inaccurate or unreadable product labeling 	<ul style="list-style-type: none"> • taking wrong dose of a drug because of confusing dosing instructions on label 	<p>drug as a brand name drug, or from another generic</p>
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Reporting Emergencies

If you have a medical emergency, call your health care professional for medical advice. If you wish to report a serious, life-threatening adverse event related to the use of an FDA-regulated product, call FDA's 24-hour emergency line at 301-443-1240 or call your local [FDA Consumer Complaint Coordinator](#).