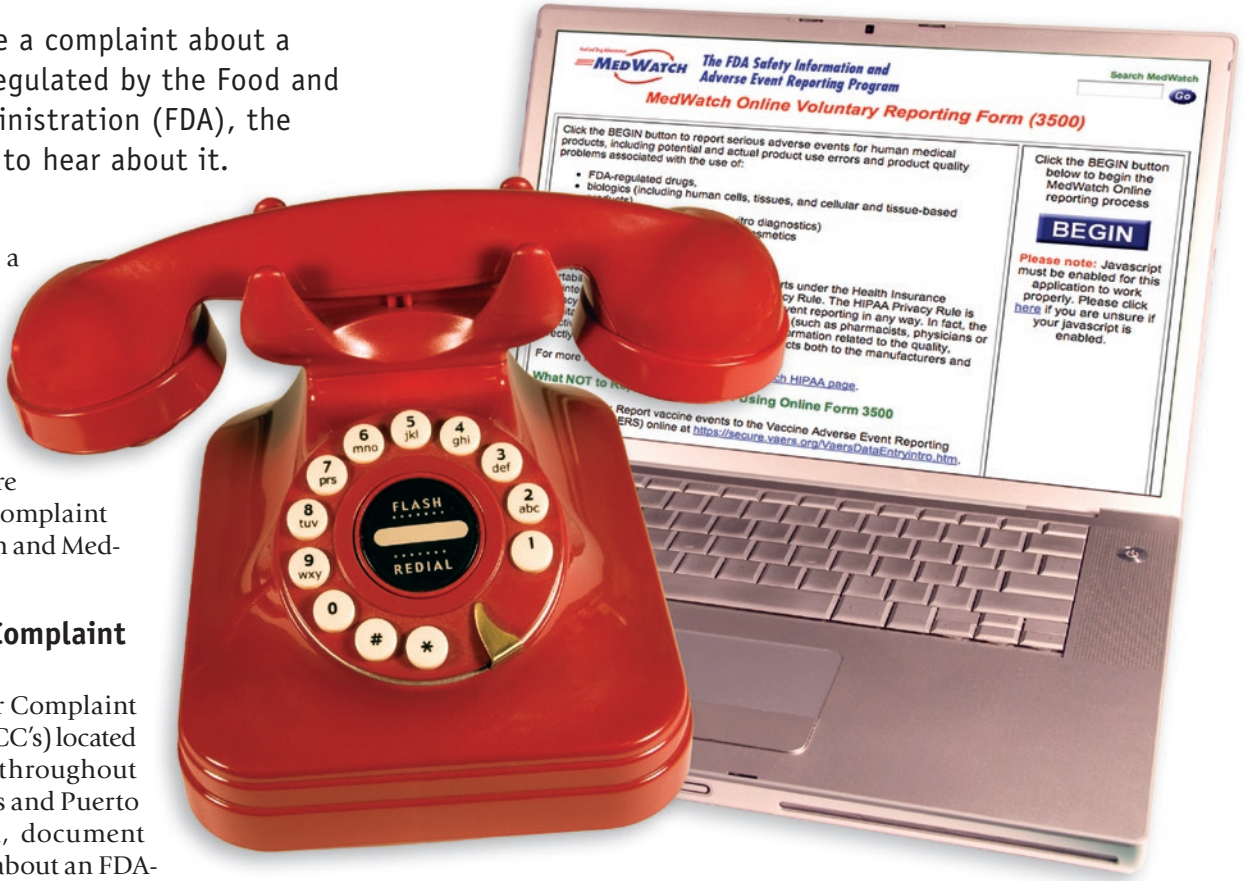
FDA 101: How to Use the Consumer Complaint System and MedWatch

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 accompanying list of CCC's. The list is also on FDA's Web site at *www.fda.gov/opacom/backgrounders/complain.html*.)

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

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.

Photo collage: FDA/Michael Ermarth

"Sometimes there are risks that only come to light after a medical product gets on the market ... "

"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.

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."

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 *www.fda.gov/medwatch/report.htm*. FDA encourages online reporting because it is the quickest and most direct route.
- **Mail**—Download the pre-addressed, postage-paid form (FDA Form 3500) at *www.fda.gov/medwatch/getforms.htm* 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 advan-

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.

tage of being able to ask questions and obtain important information that we might not get if they were filling out a MedWatch report."

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 FDA

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
• death • life-threatening situation • requires admission to hospital or longer-than-expected hospital stay • permanent disability • birth defect, miscarriage, stillbirth, or birth with serious disease • requires medical care to prevent permanent damage	• suspected counterfeit product • potentially contaminated product indicated by suspicious odor or unusual color • inaccurate or unreadable product labeling	• mixing up products with similar drug names or packaging • taking wrong dose of a drug because of confusing dosing instructions on label	• not getting same results from a generic drug as a brand name drug, or from another generic

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.

This article appears on FDA's Consumer Health Information Web page (*www.fda.gov/consumer*), which features the latest on all FDA-regulated products. Sign up for free e-mail subscriptions at *www.fda.gov/consumer/consumerenews.html*.

For More Information

Your Guide to Reporting Problems to FDA
www.fda.gov/consumer/updates/reporting_guide061008.html

MedWatch Reporting by Consumers
www.fda.gov/medwatch/report/consumer/consumer.htm

Sign Up for Free MedWatch Safety Alerts by Email
www.fda.gov/medwatch/elist.htm

FDA Consumer Complaint Coordinators

(as of February 27, 2009)

TTY: 1-800-877-8339

Region	Telephone
Alabama	866-289-3399
Alaska	800-353-3965
Arizona	949-608-3530
Arkansas	214-253-5200, ext 5233
California (Northern)	510-337-6741
California (Southern)	949-608-3530
Colorado	303-236-3044
Connecticut	781-596-7700
Delaware	215-597-9064
District of Columbia	410-779-5713
Florida	866-337-6272
Georgia	404-253-1169
Hawaii	510-337-6741
Idaho	800-353-3965
Illinois	312-353-7840
Indiana	313-393-8100
Iowa	913-752-2440
Kansas	913-752-2440
Kentucky	513-679-2700, ext 124
Louisiana	866-289-3399
Maine	781-596-7700
Maryland	410-779-5713
Massachusetts	781-596-7700
Michigan	313-393-8100
Minnesota	612-758-7221
Mississippi	866-289-3399
Missouri	913-752-2440

Region	Telephone
Montana	800-353-3965
Nebraska	913-752-2440
Nevada	510-337-6741
New Hampshire	781-596-7700
New Jersey	973-331-4917
New Mexico	303-236-3044
New York	866-446-9055
North Carolina	404-253-1169
North Dakota	612-758-7221
Ohio	513-679-2700, ext 124
Oklahoma	214-253-5200, ext 5233
Oregon	800-353-3965
Pennsylvania	215-597-9064
Rhode Island	781-596-7700
South Carolina	404-253-1169
South Dakota	612-758-7221
Tennessee	866-289-3399
Texas	214-253-5200, ext 5233
Utah	303-236-3044
Vermont	781-596-7700
Virginia	410-779-5713
Washington	800-353-3965
West Virginia	410-779-5713
Wisconsin	612-758-7221
Wyoming	303-236-3044
Puerto Rico & U.S. Virgin Islands	800-332-0127