



Your Guide to Reporting Problems to FDA



Consumers play an important public health role by reporting to the Food and Drug Administration (FDA) any adverse events (unexpected side effects) after using a medical product, or other problems with any products that the agency regulates. Timely reporting allows the agency to take prompt action. There are a number of ways you can report problems to the agency, depending on the type of problem and product. The following tips and chart will help you make your report.

Tips for Reporting

1. Report what happened as soon as possible after you discover a problem. Be prepared with the following information:
 - names, addresses, and phone numbers of people affected
 - your name, postal and e-mail address, and phone number
 - name, address, and phone number of doctor or hospital if emergency treatment was provided
 - product codes or identifying marks on the label or container
 - name and address of store where product was bought and date of purchase
 - name and address of company on the product label
2. Do not discard the product packaging and labeling. They provide codes, numbers, and dates that will help FDA trace the product back to the plant.
3. In addition to reporting to FDA, the agency recommends reporting the problem to the manufacturer and to the store where the product was purchased.
4. When in doubt about how to report a problem, call your local FDA Consumer Complaint Coordinator listed at www.fda.gov/opacom/backgrounders/complain.html.

Quick-Reference Chart for Reporting Problems to FDA

Type of Problem	Type of Product	Report to
<ul style="list-style-type: none"> emergency (serious, life-threatening event) 	<ul style="list-style-type: none"> FDA-regulated products (human drugs, animal drugs, medical devices, biological products, foods, dietary supplements, cosmetics, radiation-emitting electronic products) 	<ul style="list-style-type: none"> FDA's 24-hour emergency telephone line at either 1-866-300-4374 or 301-796-8240 FDA Consumer Complaint Coordinator in your geographic area. (See list at www.fda.gov/opacom/backgrounders/complain.html) Also contact your health care professional for medical advice.
<ul style="list-style-type: none"> serious adverse event (side effect) product quality problem (such as a medication having a suspicious odor) product use error (such as mixing up products with similar drug names or packaging) 	human health care products: <ul style="list-style-type: none"> human drugs medical devices blood products and other biologics (except vaccines) dietary supplements infant formulas medical foods such as nutritional supplements 	<ul style="list-style-type: none"> MedWatch at www.fda.gov/medwatch, or call 1-800-332-1088 to request reporting form or FDA Consumer Complaint Coordinator in your geographic area. (See list at www.fda.gov/opacom/backgrounders/complain.html) Also contact your health care professional for medical advice.
<ul style="list-style-type: none"> food-related non-emergency (such as allergic reaction to a product with no allergens listed in ingredients; a non-life-threatening foodborne illness) 	<ul style="list-style-type: none"> food products (except meat, poultry, and frozen, dried and liquid eggs) 	<ul style="list-style-type: none"> FDA Consumer Complaint Coordinator in your geographic area. (See list at www.fda.gov/opacom/backgrounders/complain.html) If problem involves meat, poultry, or frozen, dried or liquid eggs, call USDA hotline at 1-800-535-4555.
<ul style="list-style-type: none"> illness or injury related to a vaccine 	<ul style="list-style-type: none"> human vaccines 	<ul style="list-style-type: none"> Vaccine Adverse Event Reporting System (VAERS) at https://secure.vaers.org/VaersDataEntryintro.htm, or call 1-800-822-7967 to request reporting form. Also contact your health care professional for medical advice.
<ul style="list-style-type: none"> blood transfusion-related fatality 	<ul style="list-style-type: none"> blood products 	<ul style="list-style-type: none"> See www.fda.gov/cber/transfusion.htm or call 301-827-6220 or e-mail fatalities2@fda.hhs.gov.
<ul style="list-style-type: none"> clinical trials complaint 	<ul style="list-style-type: none"> clinical trials 	<ul style="list-style-type: none"> See www.fda.gov/oc/gcp/
<ul style="list-style-type: none"> cosmetic problem 	<ul style="list-style-type: none"> novelty makeup face paint other cosmetics 	<ul style="list-style-type: none"> MedWatch at www.fda.gov/medwatch, or call 1-800-332-1088 to request reporting form or FDA Consumer Complaint Coordinator in your geographic area. (See list at www.fda.gov/opacom/backgrounders/complain.html)
<ul style="list-style-type: none"> product sold online (such as product you suspect is being illegally sold or promoted on Web) 	<ul style="list-style-type: none"> FDA-regulated products sold online (human drugs, animal drugs, medical devices, biological products, foods, dietary supplements, cosmetics, radiation-emitting electronic products) 	<ul style="list-style-type: none"> See www.fda.gov/oc/buyonline/buyonlineform.htm To report e-mail promoting medical products that you think might be illegal, forward email to webcomplaints@ora.fda.gov.
<ul style="list-style-type: none"> animal food problem 	<ul style="list-style-type: none"> pet food animal feed 	<ul style="list-style-type: none"> FDA Consumer Complaint Coordinator in your geographic area. (See list at www.fda.gov/opacom/backgrounders/complain.html)
<ul style="list-style-type: none"> animal drug or device problem 	<ul style="list-style-type: none"> veterinary drugs or devices 	<ul style="list-style-type: none"> FDA's Center for Veterinary Medicine at 1-888-FDA-VETS (1-888-332-8387) or at www.fda.gov/cvm/adetoc.htm

Types of Problems FDA Doesn't Handle


Contact the agencies listed to report or complain about the following problem areas. See your local phone directory for phone numbers not provided here.

- restaurant food and sanitation—local or state health departments (check blue pages of your local phone book or find your state health department at www.cdc.gov/mmwr/international/relres.html)
- unsolicited products in the mail—U.S. Postal Service at www.usps.gov
- accidental poisonings—Poison Help at 1-800-222-1222 or local hospital
- pesticides or air and water pollution—U.S. Environmental Protection Agency at www.epa.gov/tips/
- hazardous household products (including toys, appliances, and chemicals)—U.S. Consumer Product Safety Commission hotline at 1-800-638-2772 or see www.cpsc.gov/talk.html
- alcoholic beverages—Bureau of Alcohol, Tobacco, Firearms and Explosives at www.atf.gov/contact/hotlines.htm
- drug abuse and controlled substances—U.S. Drug Enforcement Administration at www.usdoj.gov/dea/contactinfo.htm
- hazardous chemicals in the workplace—U.S. Department of Labor's Occupational Safety and Health Administration at www.osha.gov/html/Feed_Back.html
- warranties—Federal Trade Commission helpline at 1-877-FTC-HELP (1-877-382-4357) or TTY 1-866-653-4261 or see www.ftc.gov/ftc/contact.shtm
- dispensing and sales practices of pharmacies—state board of pharmacy (available at National Association of Boards of Pharmacy at www.nabp.net)
- medical practice—state certification board (check blue pages of your local phone book)

For More Information

FDA 101: How to Use the Consumer Complaint System and MedWatch
www.fda.gov/consumer/updates/reporting061008.html

Find this and other Consumer Updates at www.fda.gov/ForConsumers/ConsumerUpdates

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