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.

### Quick-Reference Chart for Reporting Problems to FDA

<table>
<thead>
<tr>
<th>Type of Problem</th>
<th>Type of Product</th>
<th>Report to</th>
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| • emergency (serious, life-threatening event)        | • FDA-regulated products (human drugs, animal drugs, medical devices, biological products, foods, dietary supplements, cosmetics, radiation-emitting electronic products) | • 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](http://www.fda.gov/opacom/backgrounders/complain.html))  
• Also contact your health care professional for medical advice. |
| • serious adverse event (side effect)                | human health care products:                                                            | • MedWatch at [www.fda.gov/medwatch](http://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](http://www.fda.gov/opacom/backgrounders/complain.html))  
• Also contact your health care professional for medical advice. |
| • product quality problem (such as a medication having a suspicious odor) | • blood products and other biologics (except vaccines)  
• dietary supplements  
• infant formulas  
• medical foods such as nutritional supplements |                                                                            |
| • product use error (such as mixing up products with similar drug names or packaging) | • food products (except meat, poultry, and frozen, dried and liquid eggs) | • FDA Consumer Complaint Coordinator in your geographic area. (See list at [www.fda.gov/opacom/backgrounders/complain.html](http://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. |
| • food-related non-emergency (such as allergic reaction to a product with no allergens listed in ingredients; a non-life-threatening foodborne illness) | • food products (except meat, poultry, and frozen, dried and liquid eggs) | • Vaccine Adverse Event Reporting System (VAERS) at [https://secure.vaers.org/VaersDataEntryintro.htm](https://secure.vaers.org/VaersDataEntryintro.htm)  
• call 1-800-822-7967 to request reporting form.  
• Also contact your health care professional for medical advice. |
| • illness or injury related to a vaccine              | • human vaccines                                                                    |                                                                            |
| • blood transfusion-related fatality                 | • blood products                                                                    | • See [www.fda.gov/cber/transfusion.htm](http://www.fda.gov/cber/transfusion.htm) or call 301-827-6220 or e-mail fatalities2@fda.hhs.gov. |
| • clinical trials complaint                          | • clinical trials                                                                   | • See [www.fda.gov/oc/gcp](http://www.fda.gov/oc/gcp)/ |
| • cosmetic problem                                   | • novelty makeup  
• face paint  
• other cosmetics | • MedWatch at [www.fda.gov/medwatch](http://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](http://www.fda.gov/opacom/backgrounders/complain.html)) |
| • product sold online (such as product you suspect is being illegally sold or promoted on Web) | • FDA-regulated products sold online (human drugs, animal drugs, medical devices, biological products, foods, dietary supplements, cosmetics, radiation-emitting electronic products) | • See [www.fda.gov/oc/buyonline/buyonlineform.htm](http://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. |
| • animal food problem                                | • pet food  
• animal feed | • FDA Consumer Complaint Coordinator in your geographic area. (See list at [www.fda.gov/opacom/backgrounders/complain.html](http://www.fda.gov/opacom/backgrounders/complain.html)) |
| • animal drug or device problem                      | • veterinary drugs or devices                                                        | • FDA’s Center for Veterinary Medicine at 1-888-FDA-VETS (1-888-332-8387) or at [www.fda.gov/cvm/adetoc.htm](http://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/refres.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
- 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