Consumers play an important public health role by reporting to the Food and Drug Administration (FDA) unexpected side effects after using a medical product, or experiencing other problems with any products that the agency regulates.

Timely reporting enables 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. When you submit a safety report through this Portal, you make a vital contribution to the safety of America's food supply, medicines, and other products that touch us all. 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 (www.fda.gov/opacom/backgrounders/complain.html). Consumers can also visit FDA’s Safety Reporting Portal (https://www.safetyreporting.hhs.gov/fpsr/WorkflowLoginIO.aspx?metinstance=5F76D992CF31E9C075D4F1F7166DE6D27CFB52976) to report a safety issue. To see a full list of products the FDA regulates, along with safety reporting information visit the safety report directory (https://www.safetyreporting.hhs.gov/fpsr/FpsrRoutingPage.aspx). Using this portal also streamlines the process of reporting product safety issues to the FDA.
### 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>
</tr>
</thead>
</table>
| • 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 [http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm](http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm))  
• Also contact your health care professional for medical advice. |
| • 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:  
• human drugs  
• medical devices  
• blood products and other biologics (except vaccines)  
• dietary supplements  
• infant formulas  
• medical foods such as nutritional supplements | • MedWatch ([http://www.fda.gov/Safety/MedWatch/default.htm](http://www.fda.gov/Safety/MedWatch/default.htm)), or call 1-800-332-1088 to request reporting form or  
• FDA Consumer Complaint Coordinator in your geographic area. (See list at [http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm](http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm))  
• Also contact your health care professional for medical advice. |
| • 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) | For all questions or problems related to meat and poultry, please contact USDA ([http://www.fda.gov/Food/ResourcesForYou/ucm334249.htm#meat_poultry](http://www.fda.gov/Food/ResourcesForYou/ucm334249.htm#meat_poultry)).  
• If you are a consumer or health professional who wants to report a product problem, an injury, or an illness related to a food or cosmetic product, please contact a FDA Consumer Complaint Coordinator (See list at [http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm](http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm)) located in the State where you reside; or if you are unable to contact a complaint coordinator, you can complete an electronic Voluntary MedWatch form ([https://www.accessdata.fda.gov/scripts/medwatch/](https://www.accessdata.fda.gov/scripts/medwatch/)) or paper Voluntary MedWatch form that can be mailed to FDA. |
| • illness or injury related to a vaccine | human vaccines | • Vaccine Adverse Event Reporting System (VAERS) at [https://secure.vaers.org/VaersDataEntryintro.htm](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.  
| • blood transfusion-related fatality | blood products | • See ([http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/TransfusionDonationFatalities/](http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/TransfusionDonationFatalities/)) or call 301-827-6220 or e-mail fatalities2@fda.hhs.gov.  
| • clinical trials complaint | clinical trials | • See Good Clinical Practice ([http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm)) in FDA-Regulated Clinical Trials  

(continued on page 3)
Quick-Reference Chart for Reporting Problems to FDA (continued)

<table>
<thead>
<tr>
<th>Type of Problem</th>
<th>Type of Product</th>
<th>Report to</th>
</tr>
</thead>
<tbody>
<tr>
<td>cosmetic problem</td>
<td>novelty makeup</td>
<td>• If you are a consumer or health professional who wants to report a product <strong>problem</strong>, an <strong>injury</strong>, or an <strong>illness</strong> related to a food or cosmetic product, please contact a FDA Consumer Complaint Coordinator (See list at <a href="http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm">http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm</a>) located in the State where you reside; or if you are unable to contact a complaint coordinator, you can complete an electronic Voluntary MedWatch form (<a href="https://www.accessdata.fda.gov/scripts/medwatch/">https://www.accessdata.fda.gov/scripts/medwatch/</a>) or paper Voluntary MedWatch form that can be mailed to FDA.</td>
</tr>
</tbody>
</table>
| • 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 ([http://www.fda.gov/Safety/ReportaProblem/ucm059315.htm](http://www.fda.gov/Safety/ReportaProblem/ucm059315.htm)) of Products on the Internet.  
• To report e-mail promoting medical products that you think might be illegal, forward email to webcomplaints@ora.fda.gov.  
• If you are a consumer or health professional who wants to report a product **problem**, an **injury**, or an **illness** related to a food or cosmetic product, please contact a FDA Consumer Complaint Coordinator (See list at [http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm](http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm)) located in the State where you reside; or if you are unable to contact a complaint coordinator, you can complete an electronic Voluntary MedWatch form ([https://www.accessdata.fda.gov/scripts/medwatch/](https://www.accessdata.fda.gov/scripts/medwatch/)) or paper Voluntary MedWatch form that can be mailed to FDA.  
| animal food problem | pet food | • FDA Consumer Complaint Coordinator in your geographic area. (See list at [http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm](http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm))  
| 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](http://www.cdc.gov/mmwr/international/refres.html))
- unsolicited products in the mail—U.S. Postal Service at [www.usps.gov](http://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/](http://www.epa.gov/tips/)
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

Sign up for free e-mail subscriptions at www.fda.gov/consumer/consumerenews.html

• 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)