

# A Guide to Drug Safety Terms at FDA

## **Adverse drug reaction**

An adverse drug reaction, also called a side effect, is any undesirable experience associated with the use of a medicine in a patient. Adverse events can range from mild to severe. Serious adverse events are those that can cause disability, are life-threatening, result in hospitalization or death, or are birth defects.

## **Boxed Warning**

This type of warning is also commonly referred to as a “black box warning.” It appears on a prescription drug’s label and is designed to call attention to serious or life-threatening risks.

**T**he Food and Drug Administration (FDA) approves a drug for marketing after determining that the drug’s benefits of use outweigh the risks for the condition that the drug will treat. But even with a rigorous evaluation process, some safety problems surface only after a drug has been on the market and has been used in a broader population. This guide offers descriptions of some of the drug safety terms commonly used by FDA throughout the life cycle of a drug.

## **FDA REVIEW**

### **Pre-Clinical Data**

Before a drug can be tested in people in the United States, sponsors (drug manufacturers, research institutions, and other organizations that develop drugs) must show FDA results of testing they have done in laboratory animals and what they propose to do for human testing.

### **New Drug Approval Process**

After the animal testing stage, FDA decides whether it is reasonably safe for the company to move forward with clinical trials—studies that evaluate the safety and effectiveness of a drug in healthy people and in patients. The drug company submits the results of such studies to FDA for review. The agency conducts a thorough review of the safety and effectiveness data, and considers how the benefits compare to the risks when making a decision of whether or not to approve a drug.

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## **TAKING MEDICATION**

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### **Medication Guides**

Medication Guides are paper handouts/pamphlets that are required to be distributed to patients with certain medications by the pharmacist. Medication Guides convey risk information that is specific to particular drugs and drug classes, and they contain FDA-approved information that can help patients avoid serious adverse events.

[www.fda.gov/cder/Offices/ODS/medication\\_guides.htm](http://www.fda.gov/cder/Offices/ODS/medication_guides.htm)

### **Consumer Medication Information (CMI)**

Compared to a Medication Guide, a Consumer Medication Information sheet offers broader information on how to use a medicine. CMI sheets are not developed or regulated by FDA. These information sheets are prepared by pharmacies and given out with prescription drugs. CMI sheets are not available on the FDA Web site. The sheets help consumers understand key information about their prescription medicine, including how to take it, how to store it, and how to monitor their treatment. The sheets also include information on precautions and warnings, as well as symptoms of serious or frequent adverse events and what to do if you experience one.

### **Prescription Drug Labeling**

Drug labeling, commonly called the package insert or the prescribing information, provides information to the physician about what a prescription medication is supposed to do, who should and should not take it, and how to use it. Labeling also includes information on a drug's side effects and warnings, and information from the clinical trials of the drug. Some prescription drug labeling also includes a part that describes

the prescribing information in words that consumers will understand.

### **Nonprescription Drug Label ("Drug Facts")**

For an over-the-counter (OTC), or nonprescription medicine, information printed on the medication bottle or package under the heading Drug Facts is important for taking care of yourself and your family. The Drug Facts tell you what a medicine is supposed to do, who should or should not take it, and how to use it. Safety information and instructions for use are displayed in a uniform and easy-to-read format.

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## **MONITORING AFTER APPROVAL**

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### **Post-Market Surveillance**

Post-market surveillance is the process by which a drug's safety is monitored on an ongoing basis after a drug is approved by FDA. Post-market surveillance seeks to identify problems that were not observed or recognized before approval and any problems that may arise because a drug may not be used as described in the drug labeling, or because a drug is being manufactured incorrectly.

### **FDA Adverse Event Reporting System (FAERS)**

FAERS is a computerized database containing reports of adverse events. It supports FDA's post-market safety surveillance program for all approved drugs and therapeutic biologics.  
[www.fda.gov/cder/aers/default.htm](http://www.fda.gov/cder/aers/default.htm)

### **MedWatch**

MedWatch is FDA's safety information and adverse event reporting program. It provides important and timely medical product information

to health care professionals, including information on prescription and over-the-counter drugs, biologics, medical devices, and special nutritional products. Health care professionals and consumers can also report serious problems they suspect are related to certain FDA-regulated products.

[www.fda.gov/medwatch/safety.htm](http://www.fda.gov/medwatch/safety.htm)

## **REMOVAL FROM THE MARKET**

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### **Drug Recall**

A drug recall is an action taken by a firm to remove a product from the market that FDA considers to be in violation of the law. Recalls are classified as Class I, Class II, or Class III. Class I recalls are the most serious and involve situations where there is a reasonable probability that the use of or exposure to a violative product, will cause serious adverse health consequences or death. A drug may be recalled due to factors such as problems with packaging, manufacturing, or contamination.

### **Drug Withdrawal**

In rare cases, FDA may need to reassess and change its approval decision on a drug. A conclusion that a drug should no longer be marketed is based on the nature and frequency of the adverse events and how the drug's benefit and risk balance compares with treatment alternatives. When FDA believes that a drug's benefits no longer outweigh its risks, the agency will ask the manufacturer to withdraw the drug.

## **TYPES OF SAFETY ANNOUNCEMENTS**

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### **Early Communication About an Ongoing Safety Review**

This type of communication is part of FDA's effort to communicate early with the public when the agency is still evaluating data and has not reached a conclusion. FDA shares information in the interest of informing doctors and patients about the issues that are under review and when FDA experts anticipate completing their review.

### Public Health Advisories

These advisories provide important drug safety information and recommendations of actions that can be taken by patients or caregivers to avoid or minimize harm from a drug. They are issued when FDA has information that would help doctors and patients make better treatment choices.

[www.fda.gov/cder/news/pubpress.htm](http://www.fda.gov/cder/news/pubpress.htm)

### Letters to Health Care Professionals

These are letters—often referred to as “Dear Doctor” letters—that are developed by drug companies often with input from FDA. The letters educate health care professionals about new and important drug information.

### Information for Health Care Professionals

Also referred to as a Healthcare Professional Information sheet, this information from FDA is for doctors, pharmacists, nurses, and other health care professionals. It contains an “alert” (a summary of the new safety information), detailed information about the safety issue, factors to consider when making treatment decisions, information for health care professionals to discuss with patients about their roles in reducing the risks from the drug, and a summary of the facts or data that serve as the basis for the information in the sheet.

### FIND THE LATEST INFORMATION

#### Index to Drug-Specific Information

This index features an alphabetical listing of drugs that have been the subject of a Public Health Advisory, a Healthcare Professional Information sheet, an Early Communication About an Ongoing Safety Review, or other important information.

[www.fda.gov/cder/drug/drugsafety/DrugIndex.htm](http://www.fda.gov/cder/drug/drugsafety/DrugIndex.htm)

#### MedWatch Alerts

MedWatch provides important and timely medical product information, and is also a venue for reporting

adverse events to FDA. You can sign up to receive MedWatch notices by e-mail. [www.fda.gov/medwatch/](http://www.fda.gov/medwatch/)

#### DailyMed

Developed with the National Library of Medicine, DailyMed is a Web site that gives physicians and patients electronic access to FDA-approved drug labels.

<http://dailymed.nlm.nih.gov>

#### Drugs@FDA

This resource allows you to search for information about FDA approved brand name and generic drugs and therapeutic biological products. These are proteins derived from living material (such as cells or tissues) used to treat or cure disease. You can search in many ways, including by drug name and active ingredient.

[www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)

#### FDA Drug Safety Podcasts

Podcasting is a method of publishing and syndicating audio broadcasts through the Internet. These provide emerging safety information about drugs in conjunction with the release of Public Health Advisories.

[www.fda.gov/cder/drug/podcast/default.htm](http://www.fda.gov/cder/drug/podcast/default.htm)

#### FDA Drug Safety Newsletter

Aimed at health care professionals, this quarterly publication is designed to enhance communication of safety information after a drug is marketed. The newsletter raises awareness of adverse events and stimulates reporting of adverse events.

[www.fda.gov/cder/dsn/default.htm](http://www.fda.gov/cder/dsn/default.htm)

#### FDA Consumer Health Information

FDA offers timely and easy-to-read articles on product approvals, safety warnings, and other health information. Articles cover all FDA-regulated products, including human drugs, drugs and feed for animals, medical devices, vaccines, blood, food, dietary supplements, and cosmetics. To find

these articles, visit the Web page at [www.fda.gov/consumer/default.htm](http://www.fda.gov/consumer/default.htm)

You can also sign up to receive notices of new consumer articles at [www.fda.gov/consumer/consumerenews.html](http://www.fda.gov/consumer/consumerenews.html)

#### Drug Product Recalls

FDA provides information on drug products that have been recalled due to manufacturing problems and/or safety concerns. In addition to information released to the public by a manufacturer using the normal media channels, FDA posts information about these recalled drug products at [www.fda.gov/opacom/7alerts.html](http://www.fda.gov/opacom/7alerts.html)


You can also sign up to receive e-mail notices of product recalls.

#### Patient Safety News

This is a televised series for health care professionals, carried on satellite broadcast networks aimed at hospitals and other medical facilities across the country. It features safety information on new drugs, biologics, and medical devices.

[www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/index.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/index.cfm) 

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