

# Postmarket Drug Safety Information for Patients and Providers

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The Food and Drug Administration has created new information sites about Postmarket Drug Safety Information for Patients and Providers. As a service, we will keep this link live on our home pages.

In accordance with Section 915 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), this website contains links to postmarket drug safety information to improve transparency and communication to patients and healthcare providers.

## Drug Labeling

- Approved Professional, Patient Labeling, and Patient Package Inserts in Drugs@FDA
- DailyMed Drug labeling on this Web site is the most recent submitted to FDA and currently in use; it may include, for example, strengthened warnings undergoing FDA review or minor editorial changes.
- List of Products with Medication Guides

## Risk Evaluation and Mitigation Strategies (REMS)

- List of REMS
- Federal Register Notice: Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007.

## Studies and Clinical Trials

## of Approved Products Required by FDA or Agreed to by the Application Holder

- Postmarket Study Requirements and Commitments  
Searchable database of CDER and CBER commitments.

## Registries and Clinical Trials

- Clinicaltrial.gov Registry and Results Databank  
ClinicalTrials.gov is a registry of federally and privately supported clinical trials conducted in the United States and around the world.Â These trials are designed primarily to evaluate the premarket efficacy and safety of drugs and biologics, as well as for new indications for products currently marketed.

## Memorandum of Agreement Between the Office of New Drugs and the Office of Surveillance and Epidemiology in the Center for Drug Evaluation and Research

- The Memorandum

## Latest Safety Information

- Index to Drug-Specific InformationÂ  
For patients, consumers, and healthcare professionals, provides links to safety sheets with the latest risk information about particular drugs, related press announcements, and other fact sheets.
- CDER What's New web page  
Includes drug safety announcements from CDER and MedWatch.
- Medical Product Safety Information from MedWatch
- FDA Drug Safety Podcasts  
Provides emerging safety information about particular drugs in conjunction with the release of Public Health Advisories.
- Drug Safety Newsletter  
This publication provides postmarket information to healthcare professionals

to enhance communication of new drug safety information, raise awareness of reported adverse events, and stimulate additional adverse event reporting.

- Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS)

- AERS Quarterly Data Files  
Access to the raw data extracted from the AERS database.

#### Reporting Problems to the FDA

- MedWatch

#### Warnings and Recalls

- Warning Letters

- Import Alerts

- Recalls, Market Withdrawals and Safety Alerts

#### Regulations and Guidance Documents

- Code of Federal Regulations, Title 21 - Food and Drugs Many FDA regulations related directly or indirectly to safety

- Selected Safety Regulations

- FDA Guidance Documents  
Many guidances relate to safety

- CDER Guidances on Drug Safety

- Guidance:  
Drug Safety Information - FDA's Communication to the Public

- Notice of Availability  
[TXT] [PDF]

Information about FDA's  
Drug Safety Oversight Board (DSB)

- DSB  
Members

- DSB  
Meetings: Public Summaries

Using Medicines Safely

- Consumer  
Education: What You Need to Know to Use Medicine Safely

- How  
to Dispose of Unused Medicines

Consumer Articles  
on Drug Safety

- Find  
the Latest Drug Product and Safety Information

- A  
Guide to Drug Safety Terms at FDA

- Spotlight  
On...Strengthening Drug Safety

- Consumer  
Update: Managing Drug Safety Issues - Questions and Answers with Paul  
Seligman, M.D., M.P.H

- Keeping  
Up With Drug Safety Information

General Health Information

- MedlinePlus Authoritative drug and health information from the National Institutes of Health (NIH), and other government agencies and health-related organizations.

FDA's Response to the Institute of Medicine's 2006 Report

- FDA  
News: FDA Reinforces Commitment to Drug Safety

- The  
Future of Drug Safety - Promoting and Protecting the Health of the Public