



Client Alert

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FDA Creates Web Page with Drug Safety Information for Patients and Health Care Professionals

Health care professionals and consumers can now go to a single page on the U.S. Food and Drug Administration's Web site to find a wide variety of safety information about prescription drugs. The consolidation of this information at one access point is aimed at helping consumers and health care professionals make well-informed decisions about medication use. The creation of the Web page was one of several requirements of the Food and Drug Administration Amendments Act of 2007 that focused on the safe use of drugs throughout their lifecycle.

The Web page, <http://www.fda.gov/cder/drugSafety.htm>, provides links to information in these key categories:

- Drug labeling, including patient labeling, professional labeling, and patient package inserts;
- Drugs that have a Risk Evaluation and Mitigation Strategy (REMS) to ensure that their benefits outweigh their risks;
- A searchable database of postmarket studies that are required from, or agreed to by, drug companies to provide the FDA with additional information about a drug's safety, efficacy, or optimal use;
- Clinicaltrials.gov, a searchable database of clinical trials, including information about each trial's purpose, who may participate, locations, and useful phone numbers;
- Drug-specific safety information, including safety sheets with the latest information about the drug as well as related FDA press announcements, fact sheets, and drug safety podcasts;
- MedlinePlus, an authoritative source for drug and health information from the National Institutes of Health and other government agencies and health-related organizations.

FDA will also post quarterly reports identifying drugs that are being evaluated for potential safety issues, based on a review of information in the FDA's Adverse Event Reporting System (AERS). Additional features include FDA regulations and guidance documents, notices of recent Warning Letters, Import



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Alerts, Recalls, Market Withdrawals, and Safety Alerts issued by FDA, and various consumer articles on drug safety.

The Web page also contains information addressing the safe use of medications by consumers, how consumers should dispose of unused medicines, and instructions on how to report problems to FDA through its MedWatch program.

A link to the FDA's response to the Institute of Medicine's 2006 report on the future of drug safety is also included.

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