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April 2008: FDA Web Site Adds Two New Pages For Learning About Drug Safety

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POSTED: Friday, April 18, 2008

 FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

The following blog post is from an independent writer and is not connected with Reuters News. The opinions and views expressed herein are those of the author and are not endorsed by Reuters.com.

Some Important Terms Are Defined And Various Research Resources From FDA Are Listed

 (Posted by Tom Lamb at [DrugInjuryWatch.com](#))

On April 11, 2008 the FDA added to its web site one page that gives short definitions for some important terms used in the realm of prescription drug safety, and another page that is intended to assist one when researching medication safety issues.

We look, first, at "[A Guide to Drug Safety Terms at FDA](#)", which begins with this introduction:

The 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.

The drug safety terms defined on this FDA web page are organized by the different stages of a drug's history. Here is a summary of the stages and terms found on this page:

1. FDA REVIEW

- Pre-Clinical Data
- New Drug Approval Process
- Adverse Drug Reaction

2. TAKING MEDICATION

- Medication Guides

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- Consumer Medication Information (CMI)
- Prescription Drug Labeling
- Nonprescription Drug Label ("Drug Facts")
- Boxed Warning

3. MONITORING AFTER APPROVAL

- Post-Market Surveillance
- Adverse Event Reporting System (AERS)
- MedWatch

4. REMOVAL FROM THE MARKET

- Drug Recall
- Drug Withdrawal

5. TYPES OF SAFETY ANNOUNCEMENTS

- Early Communication About an Ongoing Safety Review
- Public Health Advisories
- Letters to Health Care Professionals ("Dear Doctor" letters)
- Information for Health Care Professionals

The second new page at the FDA site has to do with researching the safety of prescription medications; it is titled "[Find the Latest Drug Product and Safety Information](#)".

Here are some of the FDA resources for drug safety research provided on this page:

Index to Drug-Specific Information

www.fda.gov/cder/drug/drugsafety/DrugIndex.htm

Public Health Advisories

www.fda.gov/cder/news/pubpress.htm

MedWatch Alerts

www.fda.gov/medwatch/

DailyMed

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

Drugs @ FDA

www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm

FDA Drug Safety Podcasts

www.fda.gov/cder/drug/podcast/default.htm

FDA Drug Safety Newsletter

www.fda.gov/cder/dsn/default.htm

FDA Consumer Health Information


www.fda.gov/consumer/default.htm

Recalls, Market Withdrawals and Safety Alerts

www.fda.gov/opacom/7alerts.html

We thank the FDA for posting these two new drug safety-related web pages -- both of which can be downloaded in an attractive brochure-like PDF for distribution. Furthermore, we encourage you to share these FDA materials with family and friends who may have an interest in learning more about the safety of medications that they have been prescribed or are currently using.

[Read more from this blogger at Drug Injury Watch](#) | [Let us know what you think of this feature](#)

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