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The FDA Aims To Improve Its Detection Of Drug Safety Signals powered by BlogBurst

POSTED: Wednesday, January 16, 2008

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

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Public Workshop On January 29, 2008 To Focus On Adverse Drug Reaction Reporting

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

In recent years the FDA has been roundly criticized for its failure to timely recognize emerging drug safety issues.

To improve its performance on this aspect of its work, the FDA is holding a public workshop as a means to look for ways by which to improve the collection of adverse event (AE) reports and the analysis of those reports for the purpose of better detecting drug safety "signals" in the future.

In more detail, this public workshop, "[Maximizing the Public Health Benefit of Adverse Event Collection Throughout a Product's Marketed Life Cycle](#)", will be held at The Conference Facility (terrace level) located at 5635 Fishers Lane, Rockville, MD 20857 on January 29, 2008, from 8:30 a.m. to 5 p.m., with seating on a first-come, first-served basis.

A notice about this FDA public workshop published in the Federal Register, at [72 Fed. Reg. 73029 \(Dec. 26, 2007\)](#), states that there will be a panel discussion about how the FDA currently uses spontaneous adverse event reports and other methods of drug safety signal detection. Some of the anticipated issues to be discussed include:

- What are the roles of serious and non-serious outcome AE reports in drug safety issue identification and subsequent FDA action?
- How do the roles of these AE reports change over the life-cycle of a prescription drug?
- Are there any types of AE reports that are not helpful in detecting drug safety signals?

For those unable to attend, the FDA will open a docket to receive written comments concerning issues discussed during this public workshop. That docket will remain open through February 29, 2008.

About Reuters

Information gathered at this January 29 public workshop will be used later by the FDA when the agency attempts to identify qualified organizations to do specific research about how emerging drug safety issues can be discovered as early as possible to avoid unnecessary additional adverse events in patients using unsafe drugs.

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