

FDA Now Listing Some Drugs Being Investigated

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Effective immediately, the U.S. Food and Drug Administration (FDA) will begin posting a quarterly list of drugs whose safety is under investigation over complaints brought to its attention by drug companies, physicians, and patients. Although the FDA investigates drugs because of data from clinical trials and other studies, those drugs will not be included on the list. FDA officials said they had not yet decided how to inform the public when an investigation clears a drug.

The quarterly list names drugs under review following reports to the AERS program; the first report appears on the FDA Website and covers January 1 to March 31. That report list 20 drugs, four of which are being investigated for problems already announced to the public: Heparin and anaphylaxis reactions; the diagnostic "contrast agent" Definity and cardiopulmonary reactions; Cymbalta and urinary retention; and tumor necrosis factor inhibitors and cancer in children and young adults. Other drugs listed include Tysabri for skin melanoma and phenytoin (Dilantin) injection for its association with a disorder known as Purple Glove Syndrome.

In its quarterly listing, the FDA will name the drug and the nature of its "adverse events." The FDA will not describe the seriousness of the adverse event, nor will it list the number of complaints received, officials said yesterday. Also, being placed on the list is not an indication that the drug is unsafe, rather the list indicates only that the FDA is looking into the drug and the possibility that the drug poses a safety concern. The new policy is required by changes to federal law enacted last year. FDA officials said they realize that the new policy may unintentionally alarm some patients.

Last year, the FDA's Adverse Event Reporting System (AERS) received 482,154 unsolicited reports of potential reactions to drugs. "The risk is that people will read more into this than what it is, which is a statement that an evaluation is underway," said Paul Seligman of the agency's Center for Drug Evaluation and Research. He added that he hopes patients will not stop taking a medication simply because they saw it on the list. Another official, Gerald Dal Pan, said that the FDA's "post-market surveillance" system is not changing, only the timing and extent to which the public is informed. "I think the public has told us in recent years that 'we want to know what you are working on.' We are telling the public at pretty much the earliest stage what we are working on," he said.

Sometimes rare side effects and interactions are not discovered until after a drug has gone to market and has been taken by many more people than those in pre-market studies. For instance, in recent years, the painkiller Vioxx was found to increase the risk of heart attack and stroke; the diabetes drug Avandia to increase the risk of congestive heart failure; and numerous anti-epilepsy drugs to increase suicide risk. In each of these cases, the drug's adverse reactions were not fully discovered until well after drug approval.