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FDA launches post-marketing safety website

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Direct link to the News/Story:-

http://www.fiercepharma.com/story/fda-launches-post-marketing-safety-website/2010-06-16?utm_medium=rss&utm_source=rss

FDA has unveiled its latest transparency move: Post-marketing safety reports. The agency says it will publicize internal reports it generates on the side effects of new drugs, posting those safety summaries on the FDA website every quarter. It's just part of the FDA's overall bid to keep the public more informed about what goes on at the agency--and to rebuild its image after a series of highly public safety problems, including the Vioxx debacle back in 2004.

The plan is to provide those summaries for all drugs approved after September 2007, when a law requiring FDA to generate the side-effects reports first took effect.

Its first info dump came with information on 24 drugs and two vaccines. For most of them, FDA noted no unexpected side effects and concluded that no labeling changes were necessary. In several cases--such as with Wyeth's antidepressant Pristiq and Merck's HIV drug--some troublesome adverse events were reported, but the agency decided that the reports were consistent with the drugs' current labeling. One--GlaxoSmithKline's vaccine Rotarix--has already been investigated, and its labeling changed.

Only two meds on the current list have outstanding issues. One is Sepracor's asthma drug Alvesco; FDA received reports that the drug's delivery device may be malfunctioning "after a period of use." The agency concluded that no labeling changes are needed now, but it has requested more information from the company "to further investigate this issue." The other is GlaxoSmithKline's migraine drug Treximet; the agency says it's reviewing reports of drug-administration errors.