GAO: FDA yet to make safety changes post-Vioxx

December 9 2009, By MATTHEW PERRONE , AP Business Writer

(AP) -- The Food and Drug Administration still hasn't restructured its staff to better monitor drug safety, more than three years after experts recommended key changes in the wake of the Vioxx scandal.

That's according to congressional investigators who found that the FDA has yet to follow through on changes suggested in 2006 to help the agency detect problems with drugs taken by millions of Americans. Those recommendations came after the embarrassing and dangerous episode with Vioxx, a blockbuster pain drug the FDA approved in 1999, only to pull from the market in 2004 after linking it to heart attack and stroke.

Agency officials have made some changes to drug oversight, according to a Government Accountability Office report, but the FDA continues to give the bulk of its decision-making power to scientists who approve new drugs, rather than those who monitor the side effects of drugs on the market.

"It is not yet clear if or when FDA's decision-making process will be substantially improved as a result of its efforts," according to the GAO report, a copy of which was obtained by The Associated Press.

Within the FDA bureaucracy, scientists tasked with reviewing new drug applications have traditionally had the most say over questions of safety, even after drugs are approved. But outside experts say leaving such key decisions to the scientists who first cleared the drugs could lead to

inadequate safety actions, putting prescription drug users at risk.

"There's this desire on the part of the people who first approved the drug to say, 'We predicted everything and it's fine,'" said Dr. Diana Zuckerman of the National Research Center for Women and Families in Washington.

Zuckerman and others say such decisions should be made with equal input from the FDA's office for monitoring reports of side effects collected from across the country.

The GAO, the Institute of Medicine and other experts have long recommended that the so-called Office of Surveillance and Epidemiology be given equal authority on drug safety with the agency's Office of New Drugs. But GAO investigators report that FDA leaders still have not transferred key responsibilities to surveillance officials.

"No more time should be wasted at the FDA in establishing independence for its post-market surveillance," Sen. Charles Grassley, R-Iowa, said in a statement.

Grassley - one of the agency's toughest critics in Congress - asked the GAO to follow up on its 2006 recommendations to the FDA.

The watchdog agency's report calls on the FDA to set a timetable for transferring new responsibilities to the surveillance office.

Despite a formal memo between the offices designed to put them on equal footing, the new drug office still retains nearly all the power over regulatory decisions, according to the GAO report to be released Wednesday.

In its response to the report, the FDA said major decisions about drug

safety are delegated to the new drugs division because that is "where staff with the broadest expertise and experience" on product safety issues reside.

The FDA said it intends to give the surveillance office more responsibilities, but only after its nearly 200 employees gain the experience and resources needed to take on those tasks. The Office of New Drugs has more than 900 employees.

According to the GAO, the number of surveillance staffers would have to double in coming years to accommodate the additional work being assigned to the unit.

FDA officials on Tuesday declined to comment beyond the agency's response included in the report.

Congressional investigators did note that the FDA is making progress on other safety initiatives, including:

- Revamping the computer system used to track and sort reports of drug side effects.

- Gathering more reports about possible drug safety issues from federal agencies and private medical systems.

- Developing a system to resolve drug safety disagreements between staffers.