Weather
Today: *Mostly sunny, breezy. High 64. Low 45.*
Sunday: *Partly sunny. High 69. Low 46.*
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After Criticism, FDA Will Strengthen Drug Safety Checks

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Washington Post Staff Writers

Responding to continuing criticism that it mishandled internal warnings that the painkiller Vioxx had deadly side effects and that antidepressants were being misprescribed for children, the Food and Drug Administration announced yesterday that it will strengthen its system for reviewing the safety of drugs already on the market.

Without saying that the agency had done anything wrong, acting Commissioner Lester M. Crawford outlined a series of steps the agency will take to become more aggressive about responding to reports of potentially harmful side effects.

The steps include establishing an internal program to ensure that the views of dissenting scientists are heard, a formal request to the National Academy of Sciences for a study of the FDA's safety monitoring procedures, and a renewed, nationwide search for a new director of the Office of Drug Safety. The position has been vacant for more than a year.

"We don't always understand the full magnitude of a drug's risks before it goes on the market," said Steven Galson, acting director of the FDA's Center for Drug Evaluation and Research, in a teleconference on the initiatives.

Galson rejected criticisms that the Vioxx and antidepressant episodes—when FDA scientists accused superiors of suppressing warnings about the drugs—reflected a major problem with the culture of the agency.

"It's a rarity," he said of the highly publicized disagreements. "It doesn't represent the culture, so we don't really think there is a need for an overwhelming cultural change."

Sen. Charles E. Grassley (R-Iowa), chairman of the Senate Finance Committee and recently a sharp critic of the FDA's actions, called the announcement "welcome, albeit late in coming."

"It's obvious that the leadership of the agency must take on what look like deep-rooted problems when it comes to putting public health and safety first and public relations second," Grassley said. "These initiatives need to take hold in a meaningful way and be more than an attempt to inoculate the agency in the face of alarming revelations."

Vioxx was taken off the market in September by Merck & Co. after a clinical trial was stopped because twice as many people taking the drug experienced cardiovascular disease as those taking a placebo. Several major medical journals have since published commentaries concluding that the drug should have been taken off the market earlier and criticizing the FDA for its role in keeping Vioxx on the market.

The agency also came under sharp criticism for its handling of internal reports about the possible increased risk of suicide among children prescribed antidepressants. After initially dismissing the link, the agency last month ordered all antidepressant drugs to carry a prominent

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"black box" warning to alert doctors that the medications can increase the risk of suicidal thoughts and behavior among children and adolescents.

As part of its effort to strengthen safety monitoring, the FDA will establish a formal program for agency scientists who disagree with decisions about specific drugs. The scientists will be able to present their views to a panel of FDA and outside experts, who will be required to come back with a recommendation within 30 days.

In addition, the FDA will contract with the National Academy's Institute of Medicine for a review of the safety system and an assessment of how it can learn more about potential harmful side effects before drugs become widely used. While defending the FDA's safety record, Galson said that the agency would be open to recommendations for changes.

Public health advocates generally supported the FDA's initiatives, but Sam Kazman, the chief counsel of the Competitive Enterprise Institute, a nonprofit public policy organization dedicated to the principle of limited government, said that the proposals were potentially harmful to the public health. He said he feared the agency would slow its drug review process and possibly keep useful drugs off the market.

"There's a real danger that the Vioxx situation will make the agency less willing to take any risk," he said. "Historically, the agency suffers from deadly overcaution rather than recklessness and has only been coming out of its shell in recent years. We don't want them to retreat again."

The controversy surrounding the withdrawal of Vioxx has battered Merck, which has long had the reputation of being one of the most ethical drug companies. Merck's stock closed at $26.21 Friday, down 81 cents or 3 percent for the day and down nearly 42 percent since Vioxx was withdrawn.

Merck officials declined to comment on the FDA's reform proposal, but they argued that the agency's initial news releases about the Vioxx withdrawal were very supportive of Merck's handling of the drug.

"Now people are looking at this through the prism of hindsight, and there are people with agendas who leak information to influence the process," said general counsel Kenneth C. Frazier.

Frazier and chief Merck spokeswoman Joan Wainwright said the company continues to believe it handled Vioxx appropriately. They said the company followed the FDA's guidelines for advertising and pointed out that the company promptly shared all its Vioxx studies—including the 2000 study that first suggested a heart attack risk—with the public.

"I think we still are the good drug company. We still have the same ethics," Wainwright said. "Is [the negative publicity] something I like to see every day? No, but it doesn't change the fundamentals of the company."

Merck is facing hundreds of lawsuits from Vioxx users who claim the drug harmed their health. Judges in the California and New Jersey state courts have already ruled that Vioxx-related lawsuits can be treated as class actions involving hundreds of plaintiffs. Hundreds of plaintiffs' lawyers are scheduled to gather next week in Las Vegas to coordinate efforts to bring additional cases in federal and state courts.

An estimated 20 million Americans have taken Vioxx since the drug was approved, making the number of potential plaintiffs enormous. Some Wall Street research analysts have put Merck's potential liability at more than $10 billion, fueled in part by an FDA study that estimated Vioxx could be responsible for 27,000 deaths and the conclusion in this month's Lancet, a British medical journal, that the drug should have been pulled in 2001.