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## **FDA News**

FOR IMMEDIATE RELEASE  
P04-95  
September 30, 2004

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### **FDA Issues Public Health Advisory on Vioxx as its Manufacturer Voluntarily Withdraws the Product**

The Food and Drug Administration (FDA) today acknowledged the voluntary withdrawal from the market of Vioxx (chemical name rofecoxib), a non-steroidal anti-inflammatory drug (NSAID) manufactured by Merck & Co. FDA today also issued a Public Health Advisory to inform patients of this action and to advise them to consult with a physician about alternative medications.

Merck is withdrawing Vioxx from the market after the data safety monitoring board overseeing a long-term study of the drug recommended that the study be halted because of an increased risk of serious cardiovascular events, including heart attacks and strokes, among study patients taking Vioxx compared to patients receiving placebo. The study was being done in patients at risk of developing recurrent colon polyps.

"Merck did the right thing by promptly reporting these findings to FDA and voluntarily withdrawing the product from the market," said Acting FDA Commissioner Dr. Lester M. Crawford. "Although the risk that an individual patient would have a heart attack or stroke related to Vioxx is very small, the study that was halted suggests that, overall, patients taking the drug chronically face twice the risk of a heart attack compared to patients receiving a placebo."

Dr. Crawford added that FDA will closely monitor other drugs in this class for similar side effects. "All of the NSAID drugs have risks when taken chronically, especially of gastrointestinal bleeding, but also liver and kidney toxicity. They should only be used continuously under the supervision of a physician."

FDA approved Vioxx in 1999 for the reduction of pain and inflammation caused by osteoarthritis, as well as for acute pain in adults and for the treatment of menstrual pain. It was the second of a new kind of NSAID (Cox-2 selective) approved by FDA. Subsequently, FDA approved Vioxx to treat the signs and symptoms of rheumatoid arthritis in adults and children.

At the time that Vioxx and other Cox-2 selective NSAIDs were approved, it was hoped that they would have a lower risk of gastrointestinal ulcers and bleeding than other NSAIDs (such as ibuprofen and naproxen). Vioxx is the only NSAID demonstrated to have a lower rate of these side effects.

Merck contacted FDA on September 27, 2004, to request a meeting and to advise the agency that the long-term study of Vioxx in patients at increased risk of colon polyps had been halted. Merck and FDA officials met the next day, September 28, and during that meeting the company informed FDA of its decision to remove Vioxx from the market voluntarily.

In June 2000, Merck submitted to FDA a safety study called VIGOR (Vioxx Gastrointestinal Outcomes Research) that found an increased risk of serious cardiovascular events, including heart attacks and strokes, in patients taking Vioxx compared to patients taking naproxen. After reviewing the results of the VIGOR study and other available data from controlled clinical trials, FDA consulted with its Arthritis Advisory Committee in February 2001 regarding the clinical interpretation of this new safety information. In April 2002, FDA implemented labeling changes to reflect the findings from the VIGOR study. The labeling changes included information about the increase in risk of cardiovascular events, including heart attack and stroke.

Recently other studies in patients taking Vioxx have also suggested an increased risk of cardiovascular events. FDA was in the process of carefully reviewing these results, to determine whether further labeling changes were warranted, when Merck informed the agency of the results of the new trial and its decision to withdraw Vioxx from the market.

Additional information about this withdrawal of Vioxx, as well as questions and answers for patients, is available online at

<http://www.fda.gov/cder/drug/infopage/vioxx/default.htm>.

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[FDA Public Health Advisory Questions and Answers](#)  
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