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Arthritis Health Center

Bextra Taken Off Market; Celebrex Gets Warning

Other Anti-Inflammatory Drugs Also to Carry Warnings of Heart, Stomach Risks

By [Todd Zwillich](#)

WebMD Health News

April 7, 2005 -- The popular arthritis drug Bextra will be pulled from the U.S. market under a decision issued by the FDA Thursday.

FDA officials say they asked Pfizer -- the drug's maker -- to remove it from U.S. pharmacies because its risks of heart, stomach, and skin problems clearly outweighed its benefits.

Pfizer agreed to suspend sales and marketing of Bextra in the U.S. But a company statement says it "respectfully disagrees" with the FDA's view of Bextra's risks and benefits. And Pfizer says it will talk with the FDA about ways to let the company restore Bextra's availability to doctors and patients.

Celebrex, a closely related drug also made by Pfizer, from the class of pain relievers known as Cox-2 inhibitors, will be allowed to remain on the market. But it will be forced to carry strict new warnings alerting doctors and patients that it elevates the risk of heart attacks and strokes, the FDA says.

Aspirin, Tylenol Not Included

Officials also say they are ordering new label warnings for all nonsteroidal anti-inflammatory drugs (NSAIDs) new label warnings for all nonsteroidal anti-inflammatory drugs (NSAIDs) except aspirin, including the widely sold drugs ibuprofen and naproxen.

Although aspirin is not included in this warning, regular use does increase the risk of stomach ulcer bleeding. Acetaminophen (Tylenol) is not an anti-inflammatory drug and is not included in the warnings.

Prescription forms of the drugs will now carry "black box" alerts warning of heart disease and stroke risk. Over-the-counter brands -- usually taken at lower doses and for a shorter amount of time -- must alter their labels to include more risk information. At the same time, the FDA stresses that they do not see any new increased risks associated with as-needed or short-term use of over-the-counter painkillers.

The decision is the culmination of more than seven months of public controversy [culmination of more than seven months of public controversy](#) surrounding Cox-2 drugs sparked last fall when the drug company Merck pulled Vioxx from the market because of elevated heart risks. The decision led to a broad FDA review of Cox-2 drugs and related pain relievers, including three days of scientific hearings in front of an expert advisory panel in February.

Officials Thursday said they concluded that all NSAID drugs potentially pose an elevated heart risk but that additional reports of dangerous skin reactions with Bextra effectively tipped the scales against its continued sale.

Bextra Has Special Risk

Nearly every study of Cox-2 drugs has shown that they relieve pain no better than older NSAIDs. But the drugs became popular because they are less likely than the older drugs to cause stomach bleeding.

Only a few studies have looked directly at Bextra's heart safety. One trial released in December suggested that the drug raised the risk of heart attacks in patients undergoing heart bypass surgery. Meanwhile, the FDA said it had received an abnormally high number of reports implicating Bextra in dangerous skin reactions [dangerous skin reactions](#) including toxic epidermal necrolysis and Stevens-Johnson syndrome.

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