# FDA questions wider approval of Lilly's Cymbalta

August 17 2010, By MATTHEW PERRONE , AP Business Writer

In this Jan. 25, 2006 file photo, a production technician at Eli Lilly and Company, examines Cymbalta 60mg pills in Indianapolis. The Food and Drug Administration has posted its review of Eli Lilly and Co.'s application to market the drug for a range of pain ailments, including lower back pain. FDA reviewers have questions about the statistical methods used to study the drug and liver side effects. (AP Photo/Darron Cummings, File)

(AP) -- Federal health scientists are questioning whether the antidepressant Cymbalta is safe and effective enough to be approved for use against chronic pain.

The Food and Drug Administration on Tuesday posted its review of Eli Lilly and Co.'s application to market the drug for a range of pain ailments, including lower back pain. But FDA reviewers appeared cautious about further expanding use of a powerful psychiatric drug

already used by nearly 15 million patients.

FDA reviewers raised questions about the statistical methods used to study the drug and its liver side effects.

The drug is already approved to treat depression, diabetic nerve pain and fibromyalgia.

The FDA will ask a panel of outside experts on Thursday to consider whether Cymbalta should be approved for chronic pain.

Eli Lilly has been trying to gain approval for the new indication for more than two years. The company withdrew its FDA application in November 2008 after agency evaluators questioned the method and design of some of the company's trials. The company resubmitted its application last summer with new data on Cymbalta's use against pain caused by osteoarthritis.

Three studies submitted by Lilly showed that Cymbalta lowered patient-reported pain scores significantly more than placebo after three months.

But in its review posted online, FDA scientists said Lilly's methodology still appeared "problematic." Specifically, the company included positive feedback data from patients who later dropped out of the study, possibly because of side effects to the drug. According to FDA reviewers, this practice could "potentially assign good pain scores to subjects who could not tolerate the drug."

The FDA also has concerns about widening use of a drug associated with serious liver toxicity. Cymbalta already carries a warning label about liver toxicity risks based on more than a dozen reports from patients taking the drug.

According to FDA records, use of Cymbalta has already expanded threefold - from 5 million in 2005 to 14.6 million last year - as the drug has picked up additional indications.

The agency will ask its panel of advisers to discuss the safety of further expanding the drug's use. The FDA is not required to follow the group's advice, though it often does.

A spokeswoman for Indianapolis-based Lilly said in a statement "we are confident in our data package, which is based on studying Cymbalta in more than 2,600 patients ... and we look forward to discussing our data with the committee."

Cymbalta is part of a class of drug called serotonin-norepinephrine reuptake inhibitors, which include antidepressants Effexor and Pristiq. The mechanism of action that allows Cymbalta to decrease pain is not entirely understood, though the company says it likely involves the brain chemical serotonin, which affects mood.

If approved, it would be the first antidepressant cleared for chronic pain.

The drug was Eli Lilly's second best seller last year with sales of $3 billion, behind the anti-psychotic Zyprexa.

Shares of Lilly fell 86 cents, or 2.4 percent, to $34.71 in midday trading. In a separate development Tuesday, the company announced it would abandon studies of a potential Alzheimer's disease treatment because patients taking the drug fared worse than those on a placebo.