# FDA requires Chantix, Zyban to have warning

July 1 2009

In this June 11, 2009 file photo, a customer at the Red Key Taven in Indianapolis lights a cigarette. The Food and Drug Administration on Wednesday, July 1, 2009 said it will require two smoking-cessation drugs, Chantix and Zyban, to carry the agency's strongest safety warning over side effects including depression and suicidal thoughts. (AP Photo/Darron Cummings, file)

(AP) -- The Food and Drug Administration will require two smoking-cessation drugs, Chantix and Zyban, to carry the agency's strongest safety warning over side effects including depression and suicidal thoughts.

The new requirement, called a "Black Box" warning, is based on reports of people experiencing unusual changes in behavior, becoming depressed, or having suicidal thoughts while taking the drugs.

The antidepressant Wellbutrin, which has the same active ingredient as GlaxoSmithKline PLC's Zyban, already carries such a warning.

The FDA is also requiring an additional study on Chantix and Zyban to determine the extent of the side effects. Pfizer Inc., which makes Chantix, said it is still discussing the potential study design with the FDA. The study could include patients with and without psychiatric conditions to determine the true incidence rate of psychological side effects, Pfizer officials said.

Pfizer had already updated its labeling following the beginning of an FDA investigation into the potential side effects in 2007. That investigation was sparked by several reports of psychiatric problems in patients.

Despite the new, stricter warnings, the FDA said consumers and doctors still have to weigh the benefit versus the risks when taking the drug.

"The risk of serious adverse events while taking these products must be weighed against the significant health benefits of quitting smoking," said Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research. "Smoking is the leading cause of preventable disease, disability, and death in the United States and we know these products are effective aids in helping people quit."

Last fall, the FDA also began looking into scores of patient reports about blackouts and injuries while taking Chantix. The Federal Aviation Administration later banned use of Chantix by pilots and air traffic controllers. The drug's label also warns that patients may be too impaired to drive or operate heavy machinery.

Chantix was approved in 2006. Sales reached $846 million in 2008.

"The labeling update underscores the important role of health care providers in treating smokers attempting to quit and provides specific information about Chantix and instructions that physicians and patients should follow closely," said Dr. Briggs W. Morrison, senior vice president of the primary care development group at Pfizer.

Pfizer said it made the revised label warnings in agreement with the FDA and is immediately making the information available to health care providers and patients.

Shares of Pfizer fell 11 cents to $14.89 in afternoon trading, while shares of GlaxoSmithKline rose 79 cents to $36.13.