

Pfizer anti-smoking drug needs warning: FDA

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By Kim Dixon

WASHINGTON (Reuters) - Pfizer Inc's anti-smoking drug Chantix appears increasingly likely to be linked to serious psychiatric behavior, including suicide, U.S. regulators said on Friday.

The Food and Drug Administration (FDA) said that after an analysis of cases of depression, suicidal thoughts and other unusual behavior in patients on the medication, the evidence appears stronger of an association with Chantix.

"We've become increasingly concerned as we've seen there are a number of compelling cases that truly look as if they are the result of exposure to the drug," Bob Rappaport, a director in FDA's unit that oversees Chantix, told reporters on a conference call.

Pfizer, the world's biggest drugmaker, had already updated its label to reflect the latest findings. Earlier this month it changed the label to more prominently warn that patients taking Chantix have experienced suicidal thoughts and other psychiatric behavior.

FDA officials, though, said there is rising evidence of a causal link, an assertion Pfizer has denied.

Some cases "strongly appear to be related" to Chantix, Rappaport said.

Pfizer officials have maintained there is no evidence of a causal link, and said only that in some cases an association could not be excluded. The reports could also be confounded by symptoms of nicotine withdrawal itself, Pfizer has said.

FDA officials said they have received nearly 500 reports of suicidal behavior and thinking, and 39 completed suicides. Most of these cases occurred in the United States.

About 4 million people in the United States have used the drug since its 2006 approval. Chantix had sales of \$280 million in the fourth quarter of 2007.

FDA officials said they would continue their analysis, calling it an evolving issue.

Under rising scrutiny about drugs' safety risks, the FDA has in recent months begun alerting the public earlier when it spots potential safety issues.

The FDA in November issued an "early communication" on Chantix, saying it would analyze reports of suicidal thoughts and other unusual behavior.

Chantix works by tinkering with molecules in the brain to produce some of the pleasing effects of nicotine to ease withdrawal symptoms.

The FDA said the drug is effective but that patients should talk to their doctors about this new safety information. Patients should report to doctors any history of mental illness and be alert to changes in behavior.

(Reporting by Kim Dixon, Editing by Carol Bishopric, Toni Reinhold)