FDA reviews psychiatric side effects of Chantix

April 25 2014, by Matthew Perrone

The U.S. Food and Drug Administration announced Friday it will convene a public meeting in October to review the risks of psychiatric and behavioral side effects with Pfizer's anti-smoking drug Chantix.

The agency said in a federal notice it will convene its panel of psychiatric drug experts to discuss the pill's risks and how to best manage them.

Since 2009 Chantix has carried the government's strongest safety warning—a "black box" label—because of links to hostility, agitation, depression and suicidal thoughts. The warning was added after the FDA received dozens of reports of suicide and hundreds of reports of suicidal behavior among patients taking the smoking-cessation drug.

At that time, the FDA also required Pfizer to conduct additional studies to determine the extent of the side effects.

A spokeswoman for Pfizer said Friday that the company recently submitted new data to the FDA comparing the drug's psychiatric safety to placebo and other anti-smoking techniques.

The FDA first began investigating potential side effects with Chantix in 2007, the year after the twice-a-day pill hit the market.

The drug's labeling tells patients to stop taking Chantix immediately if they experience agitation, depressed mood, suicidal thinking and other

behavioral changes. Doctors are advised to weigh the drug's risks against its potential benefits in helping patients quit smoking.

Chantix had global sales of $648 million last year. That was down about 26 percent from the drug's peak sales of $883 million in 2007, its first full year on the market.

Shares of Pfizer Inc. fell 6 cents to $30.65 in morning trading.