

FDA Issues Warning About Chantix®

February 4, 2008 -- The U.S. Food and Drug Administration (FDA) today issued a Public Health Advisory to alert health care providers, patients, and caregivers to new safety warnings concerning Chantix (varenicline), a prescription medication used to help patients stop smoking.

On Nov. 20, 2007, FDA issued an Early Communication to the public and health care providers that the agency was evaluating postmarketing adverse event reports on Chantix related to changes in behavior, agitation, depressed mood, suicidal ideation, and actual suicidal behavior.

As the agency's review of the adverse event reports proceeds, it appears increasingly likely that there may be an association between Chantix and serious neuropsychiatric symptoms. As a result, FDA has requested that Pfizer, the manufacturer of Chantix, elevate the prominence of this safety information to the warnings and precautions section of the Chantix prescribing information, or labeling. In addition, FDA is working with Pfizer to finalize a Medication Guide for patients. This is an example of FDA working with drug manufacturers throughout products' lifecycles to keep health care professionals and patients informed of new and emerging safety data.

"Chantix has proven to be effective in smokers motivated to quit, but patients and health care professionals need the latest safety information to make an informed decision regarding whether or not to use this product," said Bob Rappaport, M.D., director of the FDA's Division of Anesthesia, Analgesia and Rheumatology Products. "While Chantix has demonstrated clear evidence of efficacy, it is important to consider these safety concerns and alert the public about these risks. Patients should talk with their doctors about this new information and whether Chantix is the right drug for them, and health care professionals should closely monitor patients for behavior and mood changes if they are taking this drug."

Chantix was approved by FDA in May 2006 as a smoking cessation drug. Chantix acts at sites in the brain affected by nicotine and may help those who wish to stop smoking by providing some nicotine effects to ease the withdrawal symptoms and by blocking the effects of nicotine from cigarettes if users resume smoking.

In the Public Health Advisory and a Health Care Professional Sheet that was also issued today, FDA emphasized the following safety information for patients, caregivers, and health care professionals:

Patients should tell their health care provider about any history of psychiatric illness prior to starting Chantix. Chantix may cause worsening of current psychiatric illness even if it is currently under control. It may also cause an old psychiatric illness to reoccur. FDA notes that patients with these illnesses were not included in the studies conducted for the drug's approval.

Health care professionals, patients, patients' families, and caregivers should be alert to and monitor for changes in mood and behavior in patients treated with Chantix. Symptoms may include anxiety, nervousness, tension, depressed mood, unusual behaviors and thinking about or attempting suicide. In most cases, neuropsychiatric symptoms developed during Chantix treatment, but in others, symptoms developed following withdrawal of varenicline therapy.

Patients should immediately report changes in mood and behavior to their doctor.

Vivid, unusual, or strange dreams may occur while taking Chantix.

Patients taking Chantix may experience impairment of the ability to drive or operate heavy machinery.

FDA will continue to update health care professionals with new information from FDA's continuing review or if new information is received on Chantix and serious neuropsychiatric symptoms. FDA may consider requesting further revisions to the labeling or taking other regulatory action as the agency's continuing reviews and conclusions warrant.

For more information: <http://www.fda.gov/cder/drug/infopage/varenicline/default.htm>

Source: Food and Drug Administration