FDA News

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FDA Issues Early Communication for Chantix

Background: The U.S. Food and Drug Administration (FDA) issued an Early Communication about an Ongoing Safety Review of Chantix, a drug approved as an aid to smoking cessation treatment. An Early Communication reflects FDA's current analysis of available data concerning these drugs and does not mean that FDA has concluded that there is a causal relationship between the drug and the emerging safety issue.

FDA is evaluating postmarketing adverse event reports for Chantix (varenicline), a prescription medicine to help adults stop smoking.

Based on FDA's request for information from the manufacturer, Pfizer, Inc., the company recently submitted reports to the agency describing suicidal ideation (thoughts). In the wake of a case report citing erratic behavior in an individual who had used Chantix, FDA has also asked the company for any information on additional cases that may be similar in patients who have taken the drug.

FDA's Center for Drug Evaluation and Research is working to complete an analysis of the available information and data. When this analysis is completed, FDA will communicate the conclusions and recommendations to the public.

In the meantime, FDA recommends that health care providers monitor patients taking Chantix for behavior and mood changes. Patients taking Chantix should contact their doctors if they experience behavior or mood changes.

FDA also advises that, due to reports of drowsiness, patients should use caution when driving or operating machinery until they know how using Chantix may affect them.

Full text of the Early Communication about the Ongoing Safety Review can be found at: http://www.fda.gov/cder/drug/early_comm/varenicline.htm.

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