

FDA: New warning needed for Chantix

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The U.S. Food and Drug Administration Friday called for increased awareness of the health risks of the smoking cessation drug varenicline.

The agency said it appears increasingly likely that there may be an association between the drug, marketed by Pfizer under the name Chantix, and serious neuropsychiatric symptoms including agitation, depression, suicidal thoughts and actual suicidal behavior.

The FDA has requested that Pfizer elevate the prominence of this safety information to the warnings and precautions section of the Chantix prescribing information.

"Chantix has proven to be effective in smokers motivated to quit, but patients and healthcare professionals need the latest safety information to make an informed decision regarding whether or not to use this product," the FDA's Dr. Bob Rappaport said in a release. "While Chantix has demonstrated clear evidence of efficacy, it is important to consider these safety concerns and alert the public about these risks.

Chantix was approved by FDA in May 2006 as a smoking cessation drug.

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