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## News & Events

This is a revised version of FDA Press Release P0-65, originally issued September 29, 2005. This release was updated on Sept. 30, 2005, to indicate the correct number of trials.

## FDA NEWS RELEASE

FOR IMMEDIATE RELEASE  
P05-65  
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## FDA Issues Public Health Advisory on Strattera (Atomoxetine) for Attention Deficit Disorder

The Food and Drug Administration (FDA) today is issuing a Public Health Advisory to alert physicians of reports of suicidal thinking in children and adolescents associated with Strattera, a drug approved to treat attention deficit hyperactivity disorder (ADHD). FDA has also directed Eli Lilly and Company, manufacturer of Strattera, to develop a Medication Guide for patients and caregivers.

FDA is advising health care providers and caregivers that children and adolescents being treated with Strattera should be closely monitored for clinical worsening, as well as agitation, irritability, suicidal thinking or behaviors, and unusual changes in behavior, especially during the initial few months of therapy or when the dose is changed (either increased or decreased). Patients and caregivers who have concerns or questions about these symptoms should contact their healthcare provider.

"FDA's action today is another example of the agency acting swiftly to alert the public to significant drug safety information needed to use a drug in a safe manner," said Dr. Steven Galson, Director for the Center for Drug Evaluation and Research, FDA.

Today's actions follow a review and analysis of 11 clinical trials conducted in children with ADHD and one trial in children with enuresis (bedwetting) that identified an increased risk of suicidal thinking for Strattera. There was one suicide attempt by a patient who received Strattera among the approximately 2,200 patients in the trial. As part of a larger evaluation of psychiatric drugs and suicidality, FDA had requested that the manufacturer conduct a review of its database and clinical trials, which included more than 2200 patients--1350 patients receiving Strattera (atomoxetine) and 851 receiving a placebo. The analysis showed that 0.4% of children treated with Strattera reported suicidal thinking compared to no cases in children treated with the placebo.

Strattera, manufactured by Eli Lilly, has been on the market since 2002 and has been used in more than two million patients.

Health care professionals are encouraged to report any unexpected adverse events associated with Strattera directly to Eli Lilly, Indianapolis, Ind. at 1-800-LillyRx or to the FDA MedWatch program at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, HFD-410, 5600 Fishers Lane, Rockville, MD, 20857-9787; or online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm).