

# FDA Approves Risperdal for Two Psychiatric Conditions in Children and Adolescents

August 22, 2007 -- Rockville, MD -- The U.S. Food and Drug Administration today approved Risperdal (risperidone) for the treatment of schizophrenia in adolescents, ages 13 to 17, and for the short-term treatment of manic or mixed episodes of bipolar I disorder in children and adolescents ages 10 to 17. This is the first FDA approval of an atypical antipsychotic drug to treat either disorder in these age groups.

Until now, there has been no FDA-approved drug for the treatment of schizophrenia for pediatric use and only lithium is approved for the treatment of bipolar disorder in adolescents ages 12 and up.

“The pediatric studies of Risperdal provided an opportunity to assess the effectiveness, proper dose, and safety of using this product in the pediatric population,” said Dianne Murphy, M.D., director of FDA’s Office of Pediatric Therapeutics. “These data have permitted the identification of the effective pediatric dose ranges and have provided an evidence-based approach for treating these disorders in pediatric patients.”

The FDA first approved Risperdal in 1993 for the treatment of schizophrenia in adults. The drug later was approved for the short-term treatment of acute manic or mixed episodes associated with bipolar I disorder in adults and the treatment of irritability associated with autistic disorder in children and adolescents 5 to 16 years old.

Evidence to support this approval was collected through studies the FDA requested as part of its pediatric drug development initiatives.

The efficacy of Risperdal in the treatment of schizophrenia in adolescents was demonstrated in two short-term (6 to 8 weeks), double-blind, controlled trials. All patients were experiencing an acute episode of schizophrenia at the time of enrollment. Treated patients generally had fewer symptoms, including a decrease in hallucinations, delusional thinking, and other symptoms of their illness.

The efficacy of Risperdal in the treatment of manic or mixed episodes in children or adolescents with bipolar I disorder was demonstrated in a three-week, randomized, double-blind, placebo-controlled, multicenter trial in patients who were experiencing a

manic or mixed episode. Treated patients generally had fewer symptoms, including a decrease in their elevated mood and hyperactivity, and other symptoms of their illness.

Drowsiness, fatigue, increase in appetite, anxiety, nausea, dizziness, dry mouth, tremor, and rash were among the most common side effects reported.

Schizophrenia is a serious and disabling psychiatric disorder. Symptoms may include hallucinations, delusions, and disorganized thinking. Bipolar disorder, also known as manic-depressive illness, is a serious psychiatric disorder that causes wide shifts in a person's mood, energy, and ability to function.

For more information:

[FDA Office of Pediatric Therapeutics](#)

[National Institute of Mental Health–Schizophrenia](#)

[National Institute of Mental Health–Bipolar Disorder](#)

Source: Food and Drug Administration