



J&J drug approved to treat autism signs in children

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Last Update: Oct 9, 2006

Johnson & Johnson (JNJ) said Friday that the Food and Drug Administration approved its leading antipsychotic drug Risperdal to treat autism symptoms in children ages five to 16.

The drug is the first to be approved to treat behavior associated with autism in children, behavior that includes irritability, aggression, deliberate self-injury and temper tantrums, the FDA said.

Risperdal has been approved since 1993 for the short-term treatment of adults with schizophrenia, and since 2003 for the short-term treatment of adults with acute manic or mixed episodes associated with extreme mood swings.

The drug was Johnson & Johnson's biggest seller last year. Sales of Risperdal, including a long-acting form called Risperdal Consta, amounted to \$3.55 billion.

"While this is not a cure for autism, or even a treatment for the actual condition, we are pleased that Risperdal may provide symptom relief for some patients suffering from autistic disorder," said Johnson & Johnson spokesman Srikant Ramaswami. "We believe that this approval is a positive step toward the ultimate goal of being able to completely treat autism."

In 2005, the FDA declined to expand its approval of Risperdal to include autism.

Ramaswami said the agency at the time requested additional analysis, which was later provided by J&J.

Autism is a complex developmental disability that is usually diagnosed by the age of three. Symptoms include communication deficits and impaired social interactions.

The FDA said that two eight-week, placebo-controlled trials in 156 patients showed that children on Risperdal "achieved significantly improved scores for certain behavioral symptoms of autism compared to children on placebo."

The most common side effects of the drug included drowsiness, constipation, fatigue and weight gain.

Shares of Johnson & Johnson closed Friday at \$65.06 each, down 5 cents.