



## FDA News

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## FDA Approves the First Drug to Treat Irritability Associated with Autism, Risperdal

The U.S. Food and Drug Administration (FDA) today approved Risperdal (risperidone) orally disintegrating tablets, an adult antipsychotic drug, for the symptomatic treatment of irritability in autistic children and adolescents. The approval is the first for the use of a drug to treat behaviors associated with autism in children. These behaviors are included under the general heading of irritability, and include aggression, deliberate self-injury, and temper tantrums.

"This approval should benefit many autistic children as well as their parents and other care givers," said Steven Galson, M.D., director of FDA's Center for Drug Evaluation and Research. "Our agency strongly encourages the development of appropriate pediatric labeling for adult drugs, and Risperdal is a welcome addition to the growing number of such products that have been shown to have an appropriate risk-benefit profile when tested in children."

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 product's effectiveness in the symptomatic treatment of irritability associated with pediatric autistic disorders was established in two 8-week, placebo-controlled trials in 156 patients aged 5 to 16 years, 90 percent of whom were 5-12 years old. The results, which were evaluated using two assessment scales, 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 use of Risperdal included drowsiness, constipation, fatigue and weight gain.

Risperdal is marketed by Janssen, L.P. in Titusville, NJ.

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