FDA Approves ADHD Drug

WASHINGTON (AP) The first single-dose form of the drug most widely used to treat attention deficit disorder in children won government approval Tuesday. The Food and Drug Administration said it had approved Concerta for the treatment of attention deficit hyperactivity disorder.

Between 4 percent and 12 percent of school-age children (an average of about 2.5 million, mostly boys) are believed to have ADHD. Symptoms include short attention span, impulsive behavior and difficulty focusing and sitting still. Methylphenidate (Ritalin) often is prescribed to increase a child's alertness. But current forms of the drug require two or three doses daily, often requiring youngsters to break up their schooldays with visits to the nurse's office.

The new drug lasts 12 hours, which will avoid in-school and after-school dosing. Concerta is an extended-release formula in tablet form designed to be taken in the morning before a child leaves for school. In clinical trials the most common side effects were headaches, reported by 14 percent of patients. Less common were upper respiratory tract infection and stomachache.

Concerta was developed by Crescendo Pharmaceuticals Corp. and will be manufactured and marketed by ALZA Corp. of Mountain View, Calif. McNeill Consumer Healthcare is assisting in the marketing of Concerta, which should be available in two weeks. He said the price has not been determined but will be comparable to other ADHD treatments.

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