# Two generic versions of ADHD drug not as effective: FDA

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In some patients, the medications were released more slowly than extended-release Concerta.

(HealthDay)—Two generic versions of the attention-deficit/hyperactivity disorder drug Concerta may not work as effectively as the brand-name product does, the U.S. Food and Drug Administration said Thursday.

The agency analyzed available data and conducted laboratory tests on the two generic versions of Concerta (methylphenidate hydrochloride extended-release tablets) made by Mallinckrodt Pharmaceuticals and Kudco Ireland Ltd.

The generic versions were approved by the FDA on the basis that they released the drug in the body over a period of 10 to 12 hours, to achieve

the same effect as a three-times-per-day dose of immediate-release methylphenidate hydrochloride.

But in some patients, the two generic versions may deliver the drug in the body at a slower rate. This slower release rate means the drug may be less effective, the FDA warned.

Experts said the warning is warranted.

"This is wonderful news for patients with ADHD for whom Concerta—a long-acting formulation of Ritalin with a novel drug delivery system—has been prescribed yet have been forced to take a generic formulation with a different delivery system that did not seem to provide the same clinical benefits associated with Concerta or its generic formulation with the same drug delivery system," said Dr. Andrew Adesman, chief of developmental & behavioral pediatrics at Cohen Children's Medical Center of New York, in New Hyde Park.

"With this recent announcement, the FDA appears to be acknowledging a mistake that it made in recognizing [these] two formulations of methylphenidate as generic equivalents to Concerta," he added.

Dr. Deepan Singh, a child, adolescent and adult psychiatrist at Winthrop-University Hospital in Mineola, N.Y., said the problem is known among clinicians.

"I have made it a practice to show photographs of the original Concerta and its 'true' generic version to patients and families to ensure that the patients get the full and expected effectiveness of the medication," Singh said.

While the two other generic versions are still approved and can be prescribed, they are no longer recommended as suitable alternatives for

Concerta, the FDA said.

The agency has given Mallinckrodt Pharmaceuticals and Kudco Ireland Ltd. six months to confirm the effectiveness of their products or withdraw them from the market.

There are no serious safety concerns associated with these two generic versions of Concerta, and patients should not make changes in their drug treatment before consulting with their doctor, the FDA said.

Concerta is manufactured by Janssen Pharmaceuticals Inc., which also makes a generic version of the drug marketed by Actavis. It is identical to Concerta, the FDA said.

**More information:** The American Academy of Family Physicians has more about ADHD treatments.