

Generic pediatric AIDS Drug gets U.S. OK

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The U.S. Food and Drug Administration has tentatively approved the generic version of Abacavir Sulfate Oral Solution for use by pediatric AIDS victims.

The pharmaceutical manufactured by Aurobindo Pharma LTD. of India, is the first generic version of the already approved Ziagen Oral Solution brand of abacavir manufactured by GlaxoSmithKline.

The 20mg pediatric formulation is indicated for use in pediatric patients from 3 months through 13 years of age who are HIV infected.

The agency's tentative approval of Aurobindo's abacavir solution means that although existing patents and exclusivity prevent marketing of the product within the United States, it meets all FDA quality, safety and efficacy standards for U.S. marketing.

The tentative approval will allow the generic drug to become available for consideration for purchase and use outside the United States under the President's Emergency Plan for AIDS Relief, the FDA said.

"Saving the lives of children with HIV is a foremost goal of PEPFAR," said Gary Buehler, the director of the FDA's Office of Generic Drugs. "The agency's action ... can help bring effective treatment to thousands of infected children, and thereby dramatically brighten their future."

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