

FDA OKs 50th & 51st anti-retroviral drugs

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The U.S. Food and Drug Administration has tentatively approved nevirapine tablets and a pediatric medication used to treat the human immunodeficiency virus.

The FDA said the pediatric triple-fixed dose combination tablet of lamivudine, stavudine and nevirapine is the first fixed dose anti-HIV product designed to treat children under the age of 12 years.

The two drugs mark the 50th and 51st AIDS-related drugs approved or tentatively approved for purchase under the President's Emergency Plan for AIDS Relief.

The fixed dose combination comprises a complete HIV regimen taken twice daily and can also be dissolved in water for children who cannot swallow tablets. The FDA said the fact all three drugs are combined into one tablet that can be stored, distributed and administered easily is a significant advance in the treatment of children infected with HIV.

The FDA said its tentative approval means although existing patents or other factors prevent the sale of the products in the United States, the medications meets all U.S. manufacturing quality and clinical safety and efficacy requirements, helping ensure AIDS patients abroad can receive the same quality of medications as Americans.

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