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Strides gets tentative FDA nod for HIV generic

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Singapore: FDA has granted tentative approval to India-based Strides Arcolab's HIV drug emtricitabine and tenofovir disoproxil fumarate tablets, 200 mg/300 mg.

The drug is a generic version of Truvada, 200 mg/300 mg tablets, which is manufactured by Gilead Sciences.

The product is indicated for use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV)-1 infection.

Tentative approval implies that FDA has concluded that a drug product has met all required quality, safety and efficacy standards, but is not eligible for marketing in the US because of existing patent protections.

Tentative approval does, however, make the product eligible for purchase outside the US under the President's Emergency Plan for AIDS Relief (PEPFAR) program.