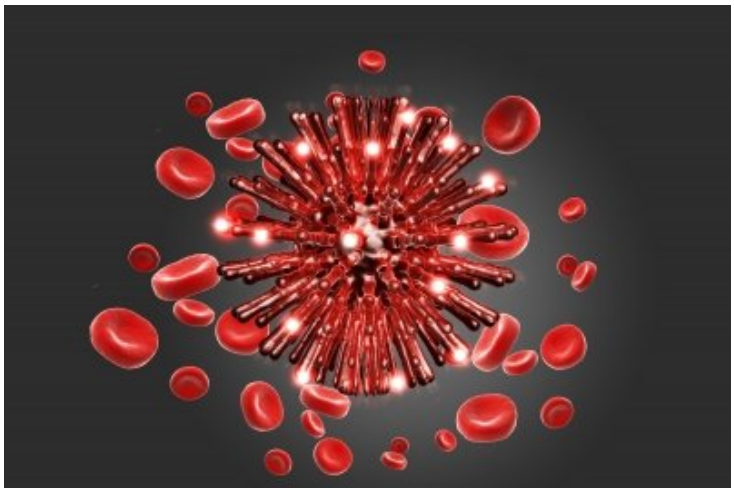
BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Cipla's HIV drug gets tentative nod from FDA

February 27, 2014 | News | By BioSpectrum Bureau



Singapore: India based generic drug maker Cipla has recieved FDA tentative approval for a generic formulation of emtricitabine and tenofovir disoproxil fumarate tablets, 200 mg/300 mg.

The fixed dose combination drug, indicated for use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV)-1 infection, is a generic version of Truvada tablets, manufactured by Gilead Sciences.

The application was reviewed under the expedited review provisions of the President's Emergency Plan for AIDS Relief (PEPFAR).

"Tentative approval" means 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 U.S. because of existing patent protections. Tentative approval does, however, make the product eligible for purchase outside the United States under the PEPFAR program.