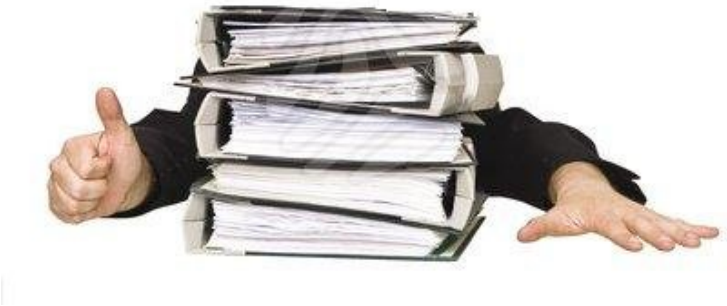
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FDA clears 152 antiretroviral drugs for HIV/AIDS program

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Singapore: The US Food and Drug Administration (FDA) has approved or tentatively approved a total of 152 antiretroviral drugs in association with the President's Emergency Plan for AIDS Relief (PEPFAR) to treat those infected with HIV/AIDS in countries that lack the tools needed to fight the AIDS epidemic.

Cipla's generic drugs lopinavir and ritonavir oral solution apart from abacavir oral solution by Hetero Labs and efavirenz tablets by Edict Pharmaceuticals have received tentative approvals from the FDA for PEPFAR. US FDA Commissioner Ms Margaret A Hamburg made the announcement on July 23, 2012.

Tentative approval means that although FDA has found that a drug product has met all required manufacturing quality, clinical safety, and efficacy requirements, it cannot be approved for marketing in the US at this time because of existing patents or marketing exclusivity. However, the product is eligible for purchase outside the US through the PEPFAR program. All FDA reviews of drug applications received in association with PEPFAR are expedited, as are any inspections of the overseas manufacturing facilities.

Established in 2003, the PEPFAR program seeks to prevent, treat, and care for those infected with and affected by HIV/AIDS worldwide. It is a cooperative effort that involves the FDA and other Department of Health and Human Services agencies, the State Department's Office of the US Global AIDS Coordinator, US Department of Defense, other federal agencies, host country governments, and many international partners. PEPFAR represents the largest commitment by any nation to combat a single disease.

The antiretroviral drug products either fully or tentatively approved by the FDA under PEPFAR include innovative formulations such as fixed-dose combination and co-packaged products that can be used alone as complete regimens or in combination with other antiretroviral drugs. The products also include tablets for adults, as well as tablet formulations that can be dispersed in water for children who are unable to swallow tablets, making it easier for infected individuals to take and adhere to their medications.

The PEPFAR program has supported life-saving antiretroviral treatment for more than 3.9 million men, women, and children worldwide as of Sept. 30, 2011, the most recent figure available. In fiscal 2011, PEPFAR directly supported antiretroviral drug prophylaxis to prevent mother-to-child HIV transmission for more than 660,000 HIV-positive pregnant women, allowing more than 200,000 infants to be born HIV-free.