Generic Approval of Tivicay (Dolutegravir) Sought for PEPFAR Use

June 2, 2015

ViiV Healthcare, Aurobindo Pharma and the Clinton Health Access Initiative (CHAI) have announced that Aurobindo has submitted an abbreviated new drug application (ANDA) to the U.S. Food and Drug Administration (FDA) for tentative approval of Tivicay (dolutegravir). Tentative approval would mean that, following completion of local regulatory approval processes in specific foreign nations, the generic dolutegravir would be available for use by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), which provides HIV treatment mainly to sub-Saharan African nations.

ViiV and CHAI have a collaboration agreement, running nearly five years, to bring new medications to people living with HIV in developing nations on an affordable and sustainable basis.

Aurobindo is an India-based pharmaceutical company. Generic drugs are often manufactured in India due to a large local industry that manufactures to the highest international standards..

To read the ViiV press release, click here.

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http://beta.docker.poz.com/article/dolutegravir-PEPFAR-27333-3827