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Cipla receives USFDA nod to market its HIV drug

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Cipla has received final nod from the United States Food and Drug Administration (USFDA) for its abbreviated new drug application (ANDA) for Efavirenz tablets in 600mg strength

Drug major Cipla on Tuesday said it has received approval from the US health regulator to market Efavirenz tablets, used to treat HIV-1 infections in adults.

The Mumbai-based firm has received final nod from the United States Food and Drug Administration (USFDA) for its abbreviated new drug application (ANDA) for Efavirenz tablets in 600mg strength, Cipla said in a statement.

The product is available for shipping immediately, it added.

Cipla's product is the generic version of Bristol-Myers Squibb Pharma Company's Sustiva which is indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 infection in adults.

As per IQVIA (IMS Health), Sustiva and its generic equivalents had US sales of around USD 105 million for the 12-month period ending April 2018.