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Sun Pharma gets FDA approval for generic Gleevec

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Sun Pharmaceutical has announced that one of its subsidiaries has received final approval from the US FDA for its Abbreviated New Drug Application (ANDA) for generic version of Gleevec, Imatinib Mesylate tablets 100mg and 400mg.

Imatinib Mesylate tablets, 100 mg and 400 mg are therapeutic equivalents of Novartis' Gleevec tablets.

As per IMS MAT August 2015, these tablets have annual sales of approximately $2.5 billion in the US. These tablets are indicated for the treatment of chronic myeloid leukemia.

The Sun Pharma subsidiary, being the first-to-file an ANDA for generic Gleevec with a para IV certification, is eligible for 180-days marketing exclusivity in the US.

Under the terms of a settlement agreement with Novartis, the Sun Pharma subsidiary is permitted to launch its version of generic Gleevec in the United States on February 1, 2016.