

Lupin gets FDA nod to make generic insomnia drug

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Singapore: The US FDA provided its final approval to Indian drug maker Lupin to manufacture and market a generic version of Sanofi Aventis' Ambien CR extended release tablets.

Zolpidem Tartrate extended release tablets 6.25 mg and 12.5 mg are advised for the treatment of insomnia, which is characterized by difficulties with sleep onset and sleep maintenance.

Lupin said in a release that its wholly-owned US subsidiary, Lupin Pharmaceuticals (LPI), will start marketing the product soon. Lupin has received 86 approvals so far until the quarter of June 30, 2013. Lupin's cumulative abbreviated new drug application (ANDA) filings with the US FDA stands at 177.