FDA approves Lupin's sleep-disorder generic

The approved drug is bioequivalent to Harmony Biosciences' WAKIX (pitolisant), which is indicated for the treatment of excessive daytime sleepiness (EDS) or cataplexy in patients with narcolepsy.

Mumbai: Drug maker Lupin Limited announced that the the US Food and Drug Administration (FDA), has granted final approval o its for Abbreviated New Drug Application for pitolisant tablets.

The approved drug is bioequivalent to Harmony Biosciences' Wakix, which is indicated for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients with narcolepsy.

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Lupin did not disclose the drug's expected market potential and launch timeline.

News Source:

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