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FDA nod for Aurobindo generic migraine tablets

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Bangalore: The US FDA granted final approval to India-based Aurobindo Pharma to manufacture and market rizatriptan benzoate tablets used in the treatment of migraine. The product, which is the generic equivalent of Merck and Co's Maxalt tablets, had previously got tentatively approval from the FDA.

Aurobindo is ready to launch 5mg (base) and 10mg (base) tablets, which are indicated for the acute treatment of migraine with-or-without aura in adults and in pediatric patients aged from six-to-17 years.

Data by IMS estimates the annual sale of the product to be approximately worth $300 million for 12 months ending March 2012. The product has been approved out of unit VII (SEZ) formulations facility in Hyderabad, India. Aurobindo now has a total of 171 abbreviated new drug application (ANDA) approvals (146 Final approvals including two from Aurolife Pharma and 25 tentative approvals) from the FDA.