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FDA approves Aurobindo's epilepsy drug

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Singapore: The US Food & Drug Administration (USFDA) has granted approval for Aurobindo Pharma's epilepsy prevention drug Lacosamide. Aurobindo Pharma is India's leading drugmaker.

Epilepsy is the fourth common neurological disorder that affects all ages. Characterized by unprovoked seizures, epilepsy is achronic disorder that may lead to sudden death. According to a WHO statistcs, nearly 15 million people in Asia are suffering form this disorder.

Aurobindo now has a total of 257 ANDA approvals (221 Final approvals including 11 from Aurolife Pharma LLC and 36 tentative approvals) from USFDA. This is the 73rd ANDA (including 15 tentative approvals) to be approved out of Unit VII formulation facility in Hyderabad, India for manufacturing Oral Non-Antibiotic products.

According to an IMS data the approved product has an estimated market size of $782 million for the twelve months ending February 2016. In a BSE filing, Aurobindo Pharma said, "The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Vimpat Tablets, 50 mg, 100 mg, 150 mg and 200 mg of UCB, Inc."