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Aurobindo gets USFDA nod for bipolar disorder drug

OUR BUREAU
Hyderabad, June 3

Aurobindo Pharma Ltd has received final approval from the US Food & Drug Administration (USFDA) to manufacture and market Divalproex sodium extended-release tablets. The product is ready for launch. The drug is the generic equivalent of AbbVie Inc's Depakote ER extended-release tablets and indicated for the treatment of acute manic or mixed episodes associated with bipolar disorder, with or without psychotic features. The product has a market size of approximately $ 690 million for the twelve months ending March 2014 according to IMS. "This ANDA has been approved out of Unit VII (SEZ) formulation facility in Hyderabad," the company said in a release issued here.

Aurobindo now has a total of 194 ANDA approvals (168 final approvals, including 7 from Aurolife Pharma LLC and 26 tentative approvals) from USFDA.