

Glenmark receives tentative approval for new generic

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Glenmark Pharmaceuticals USA (Glenmark) has been granted tentative approval by the United States Food and Drug Administration (US FDA) its Lacosamide Oral Solution, 10 mg/mL, the generic version of Vimpat Oral Solution, 10 mg/mL of UCB, Inc.

Glenmark will market this product upon receiving final approval of its Lacosamide Oral Solution, 10 mg/mL ANDA. The patent listed in the Orange Book for Vimpat Oral Solution, 10 mg/mL is scheduled to expire on March 17, 2022.

According to IMS Health sales data for the 12 month period ending January 2016, the Vimpat market achieved annual sales of approximately \$55.4 million.