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Glenmark receives tentative ANDA approval for Topiramate

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Glenmark Pharmaceuticals Inc., has been granted tentative approval by the United States Food & Drug Administration (U.S. FDA) for Topiramate Extended-Release Capsules, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg.

It is a generic version of QUDEXY®1 XR Extended-Release Capsules, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg, of UpsherSmith Laboratories, LLC.

According to IQVIATM sales data for the 12 month period ending November 2018, the QUDEXY® XR Extended-Release Capsules, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg market2 achieved annual sales of approximately $84.0 million.

Glenmark’s current portfolio consists of 148 products authorized for distribution in the U.S. marketplace and 54 ANDA’s pending approval with the USFDA.

In addition to these internal filings, Glenmark continues to identify and explore external development partnerships to supplement and accelerate the growth of its existing pipeline and portfolio.