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Glenmark receives tentative ANDA approval for generic version of Tecfidera® Capsules

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Glenmark Pharmaceuticals has been granted tentative approval by the United States Food & Drug Administration for Dimethyl Fumarate Delayed-Release Capsules, 120 mg and 240 mg, a generic version of Tecfidera® Capsules, 120 mg and 240 mg, of Biogen Inc.

According to IQVIATM sales data for the 12 month period ending August 2019, the Tecfidera® Capsules, 120 mg and 240 mg market achieved annual sales of approximately $3.7 billion.

Glenmark's current portfolio consists of 161 products authorized for distribution in the US marketplace and 49 ANDA's pending approval with the USFDA.