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Glenmark gets ANDA approval for Hydrocortisone Valerate Ointment

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It is a generic version of Westcort® 1 Ointment, 0.2%, of Sun Pharmaceutical Industries

Glenmark Pharmaceuticals Inc.,(Glenmark) has been granted final approval by the United States Food & Drug Administration (U.S. FDA) for Hydrocortisone Valerate Ointment USP, 0.2%, a generic version of Westcort® 1 Ointment, 0.2%, of Sun Pharmaceutical Industries, Inc. Glenmark has been granted a competitive generic therapy (CGT) designation for Hydrocortisone Valerate Ointment USP, 0.2%, therefore, with this approval, Glenmark is eligible for 180 days of CGT exclusivity upon commercialization. This is Glenmark's first granted CGT product approved by the FDA.

According to IQVIATM sales data for the 12 month period ending October 2018, the Westcort® Ointment, 0.2% market2 achieved annual sales of approximately $11.1 million*.

Glenmark's current portfolio consists of 145 products authorized for distribution in the U.S. marketplace and 55 ANDA's pending approval with the U.S. FDA.

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.