

Glenmark gets tentative ANDA 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) for its Azelaic Acid Gel, 15 percent, the generic version of Finacea Topical Gel, 15 percent of Bayer Healthcare.

Glenmark will market this product upon receiving final approval of its Azelaic Acid Gel, 15 percent ANDA. The patent listed in the Orange Book for Finacea Topical Gel, 15 percent is scheduled to expire on November 18, 2018.

According to IMS Health sales data for the 12 month period ending December 2015, the Finacea market achieved annual sales of approximately \$128.0 million.

Glenmark's current portfolio consists of 106 products authorized for distribution in the US marketplace and 62 ANDA's pending approval with the USFDA.