

Glenmark gains FDA approval for new generic

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Glenmark Pharmaceuticals USA (Glenmark) has been granted final approval by the United States Food and Drug Administration (US FDA) for Norgestimate and Ethinyl Estradiol Tablets USP, 0.18 mg/0.025 mg, 0.215 mg/0.025 mg, and 0.25 mg/0.025 mg.

Glenmark's drug is the generic version of Ortho Tri-Cyclen Lo Tablets of Janssen Pharmaceuticals.

According to IMS Health sales data for the 12 month period ending December 2015, the Ortho Tri-Cyclen Lo Tablets market¹ achieved annual sales of approximately \$503.9 million.

Glenmark's current portfolio consists of 107 products authorized for distribution in the US marketplace and 62 ANDA's pending approval with the FDA.