

Glenmark's new generic drug gets FDA nod

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Glenmark Pharmaceuticals (Glenmark) has been granted final approval by the United States Food and Drug Administration (US FDA) for the extended-cycle oral contraceptive, Levonorgestrel/Ethinyl Estradiol Tablets USP, 0.15 mg/0.03 mg, the AB-rated generic version of Seasonale by Teva Women's Health.

Seasonale is indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception. According to IMS Health sales data for the 12 month period ending April 2015, the Seasonale market achieved annual sales of approximately \$53.7 million.

This approval marks Glenmark's 12th oral contraceptive and second extended-cycle oral contraceptive authorized for distribution by the US FDA. The company plans to commence shipping of Levonorgestrel/Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg immediately.