

Glenmark receives two ANDA approvals from the FDA

29 March 2016 | News | By BioSpectrum Bureau

Glenmark receives two ANDA approvals from the FDA



Glenmark Pharmaceuticals USA (Glenmark) has been granted final approval by the United States Food and Drug Administration (US FDA) for Drospirenone and Ethinyl Estradiol Tablets USP, 3 mg/0.03 mg.

Glenmark's products are the generic version of Yasmin Tablets of Bayer HealthCare Pharmaceuticals and for Levonorgestrel Tablet, 1.5 mg, the generic version of Plan B One-Step Tablet of Teva Branded Pharmaceutical Products R&D for over-the-counter (OTC) use as recommended in the submitted labeling.

According to IMS Health sales data for the 12 month period ending January 2016, the Yasmin market¹ achieved annual sales of approximately \$131.7 million.

According to IMS Health sales data for the 12 month period ending January 2016, the Plan B One-Step Tablet OTC market¹ achieved annual sales of approximately \$45.2 million.