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Glenmark Generics Receives FDA Nod For Norethindrone Contraceptive Tablets

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Direct link to the News/Story:-

http://regulatoryaffairs.pharmaceutical-business-review.com/news/glenmark_generics_receives_fda_nod_for_norethindrone_contraceptive_tablets_100723/

Glenmark Generics Inc, a subsidiary of group firm Glenmark Generics Ltd, has received FDA approval for Norethindrone tablets 0.35mg. Glenmark has said that Norethindrone is the generic version of Ortho McNeil Janssen Pharmaceuticals' Micronor.

Glenmark's Norethindrone tablets are a progestin-only oral contraceptive indicated for the prevention of pregnancy. It works by suppressing ovulation, thickening cervical mucus to prevent sperm penetration, and altering the lining of the uterus.

Additionally, Estradiol/Norethindrone is a combination of estrogen and progestin hormones. It works by replacing natural progestin and estrogen in women who can no longer produce enough of these hormones. Currently, Glenmark has existing abbreviated new drug applications (ANDAs) pending approval with the FDA along with additional products in various stages of development within this oral contraceptive therapeutic segment.

Glenmark Generics Limited (GGL) primarily sells its FDF products in the US and the EU, as well as its oncology FDF products in South America.