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Tentative FDA approval for Glenmark's new generic drug

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Glenmark Pharmaceuticals USA (Glenmark) has been granted tentative approval by the United States Food & Drug Administration (US FDA) for Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.01 mg, Ethinyl Estradiol Tablets USP, 0.01 mg and Ferrous Fumarate Tablets, 75 mg.

The drug is the generic version of Lo Loestrin Fe (norethindrone acetate and ethinyl estradiol, ethinyl estradiol and ferrous fumarate) Tablets of Allergan Pharms Intl.

Glenmark will market this product upon receiving final approval of its Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.01 mg, Ethinyl Estradiol Tablets USP, 0.01 mg and Ferrous Fumarate Tablets, 75 mg ANDA.

The patent listed in the Orange Book for Lo Loestrin Fe (norethindrone acetate and ethinyl estradiol, ethinyl estradiol and ferrous fumarate) Tablets is scheduled to expire on February 2, 2029.

According to IMS Health sales data for the 12 month period ending February 2016, the Lo Loestrin Fe market achieved annual sales of approximately $432.2 million.