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FDA nod for Glenmark's new generic drug

07 April 2015 | News | By BioSpectrum Bureau

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Glenmark Generics has been granted the final abbreviated new drug approval (ANDA) from the United States Food and Drug Administration (US FDA) for Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 0.5 mg/2.5 mcg and 1 mg/5 mcg. Glenmark will commence distribution of the product immediately.

These tablets are Glenmark's generic version of Warner Chilcott's FemHRT. The drugs are indicated for the treatment of moderate to severe vasomotor symptoms due to menopause and for the prevention of postmenopausal osteoporosis in women at significant risk of osteoporosis.

For the 12 month period ending February 2015, the FemHRT market garnered annual sales of $38.6 million, according to IMS Health.