

Famy Care receives US FDA approval for generic Nordette 28 tablets

Pittsburgh

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The US Food and Drug Administration (FDA) has granted final approval for Famy Care's Abbreviated New Drug Application (ANDA) for levonorgestrel and ethinyl estradiol tablets USP, 0.15 mg/0.03 mg. This product is the generic version of Teva Branded Pharmaceutical Products' Nordette 28 tablets, which are indicated for the prevention of pregnancy in women who elect to use this product as a method of contraception.

The product will be distributed in the US by Mylan Pharmaceuticals Inc., and the company is shipping product immediately.

Heather Bresch, CEO, Mylan said, "The approval and immediate launch of our levonorgestrel and ethinyl estradiol tablets USP, 0.15 mg/0.03 mg, represents an exciting advance for the women's health care franchise that Mylan is establishing in partnership with Famy Care Ltd., one of the world's largest manufacturers of oral contraceptives. Presently, we have 34 oral contraceptives pending approval with the FDA and expect to receive additional approvals of these products beginning in next year's first quarter."

Levonorgestrel and ethinyl estradiol tablets USP, 0.15 mg/0.03 mg, had US sales of approximately \$60.4 million for the 12 months ending Sept. 30, 2012, according to IMS Health.

Currently, Mylan has 185 ANDAs pending FDA approval representing \$80.6 billion in annual sales, according to IMS Health. Thirty-five of these pending ANDAs are potential first-to-file opportunities, representing \$21.2 billion in annual brand sales, for the 12 months ending June 30, 2012, according to IMS Health.

Mylan is a global pharmaceutical company committed to setting new standards in health care.