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Lupin gets FDA approval to market Lutera

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Singapore: Pharma major Lupin has received final approval for its Levonorgestrel and Ethinyl Estradiol Tablets USP, 0.1 mg / 0.02 mg from the US Food and Drugs Administration (US FDA) to market a generic version of Watson Laboratories' Lutera 28 Tablets.

Lupin's Levonorgestrel and Ethinyl Estradiol tablets are a combined oral contraceptive indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception. Lupin will be marketing its generic product shortly.

Lutera tablets had annual US sales of approximately $103.6 million (IMS MAT Sept 2012 sales).

Lupin entered the US oral contraceptives market with the launch of its generic for NOR QD in September 2011 and has the largest OC pipeline for the US market, with 32 filings with the US FDA and has received seven approvals so far. In December 2012, the company also launched the generic for Yasmin, which has annual sales of approximately USD 275.1 million (IMS MAT Sept 2012 sales).