

Sun Pharma generic testosterone injection gets FDA nod

06 June 2013 | Regulatory | By BioSpectrum Bureau



Mumbai: Sun Pharmaceutical Industries received final approval from the US FDA for its abbreviated new drug application (ANDA) for Testosterone Cypionate injection, 100 mg/ml and 200mg/ml, which is a generic version of Depo-Testosterone injection.

The generic Testosterone Cypionate Injection is therapeutically equivalent to Depo-Testosterone injection of Pfizer and is indicated for replacement therapy in males, whose conditions are associated with symptoms of deficiency or absence of endogenous testosterone. It is estimated that the product clocked annual revenues of approximately \$130 million in the US in 2012.