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Sun Pharma gets US FDA nod for generic Namenda tablets

Friday, May 07, 2010 13:15 IST
Our Bureau, Mumbai

Sun Pharmaceutical's US subsidiary has received US FDA approval to market a generic version of Forest Laboratories, Inc Namenda 5 mg and 10 mg tablets. Sun was amongst the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification to the 703 patent. Sun's subsidiary is eligible for 180 days generic exclusivity.

These generic Memantine tablets are equivalent to Forest Laboratories, Inc's Namenda tablets and include two strengths: 5 mg and 10 mg. These strengths of Memantine have a combined annual sale of approximately US$ 1.2 billion in the US.

Memantine tablets are indicated for the treatment of moderate to severe Alzheimer's Disease. Namenda is a registered trademark of Forest Laboratories, Inc., licensed from Merz Pharmaceuticals GMBH.