

## Sun Pharma announces USFDA approval for generic Prandin® Company has 180-day marketing exclusivity

30 November -0001 | News | By BioSpectrum Bureau

### Sun Pharma announces USFDA approval for generic Prandin® Company has 180-day marketing exclusivity



Sun Pharmaceutical Industries recently announced that the US FDA has granted its subsidiary final approval for its Abbreviated New Drug Applications (ANDA) for generic version of Prandin®, Repaglinide tablets.

Repaglinide tablets, 1 mg and 2 mg are therapeutic equivalents of Novo Nordisk's Prandin® tablets. These tablets have annual sales of approximately USD 200 million in the US. Repaglinide tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type-2 diabetes mellitus.

Sun Pharma's subsidiary, being the first-to-file an ANDA for generic Prandin® with a para IV certification, is eligible for a 180-day marketing exclusivity in the US.

Established in 1983, listed since 1994 and headquartered in India, Sun Pharmaceutical Industries is an international, integrated, speciality pharmaceutical company. It manufactures and markets a large basket of pharmaceutical formulations as branded generics as well as generics in India, US and several other markets across the world. In India, the company is a leader in niche therapy areas of psychiatry, neurology, cardiology, nephrology, gastroenterology, orthopedics and ophthalmology. The company has strong skills in product development, process chemistry, and manufacturing of complex API, as well as dosage forms.