

Sun Pharma receives tentative USFDA approval for Januvia

15 April 2013 | News | By BioSpectrum Bureau

Sun Pharma receives tentative USFDA approval for Januvia



The US FDA has granted Sun Pharmaceuticals two tentative approvals for its Abbreviated New Drug Applications (ANDA) for generic version of Januvia, Sitagliptin Tablets and generic version of Glumetza, Metformin HCl extended-release tablets. Sitagliptin tablets, are therapeutic equivalents of Merck Sharp & Dohme Corporation's (MSD) Januvia tablets.

Januvia recently found itself in the news for legal reasons, when MSD has filed a patent suit in India's Delhi High Court against Glenmark, alleging a violation of its patent for blockbuster anti-diabetes drugs Januvia and Janumet. Sun Pharma had earlier entered into an agreement with MSD for marketing, promoting and distributing MSD's diabetes products in India, including Januvia and Janumet in 2011.

Sitagliptin tablets have annual sales of approximately USD 2.7 billion in the US. Sitagliptin tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type-2 diabetes mellitus.

Metformin HCl extended-release tablets are therapeutic equivalents of Santarus Glumetza tablets. Metformin HCl extended-release tablets have annual sales of approximately USD140 million in the US and are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type-2 diabetes mellitus.