

Sun gets FDA nod for Januvia, Glumetza generics

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Mumbai: Sun Pharmaceutical subsidiary received two tentative approvals from the US FDA 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, 25 mg, 50 mg and 100 mg are therapeutic equivalents of Merck Sharp & Dohme's Januvia tablets. Sitagliptin tablets have annual sales of approximately \$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, 500 mg and 1000 mg are therapeutic equivalents of Santarus Glumetza tablets. Metformin HCl extended-release tablets have annual sales of approximately \$140 million in the US. Metformin HCl extended-release tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type-2 diabetes mellitus.