BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

First generic of diabetes drug Actos approved

20 August 2012 | News | By BioSpectrum Bureau

US FDA approves world's first generic of diabetes drug Actos

Singapore: The US FDA has approved world's first generic version of Actos (pioglitazone hydrochloride) tablets. US-based pharma company Mylan Pharmaceuticals, received FDA approval for 15 milligram, 30 mg and 45 mg pioglitazone tablets. Along with diet and exercise, pioglitazone is used to improve blood glucose control in adults with type 2 diabetes.

"Controlling blood sugar levels is very important in preventing or reducing the long-term health complications of diabetes," said Gregory P Geba, director of the Office of Generic Drugs in FDA's Center for Drug Evaluation and Research. "Generic versions of this widely used product will offer affordable treatment options for patients who must manage this chronic and potentially serious condition."

Pioglitazone is dispensed with a patient Medication Guide that provides important instructions about its use and drug safety information. The drug has a Boxed Warning to emphasize that pioglitazone may cause or worsen heart failure, particularly in certain patient populations. Careful monitoring of patients when starting the drug or increasing the dose is recommended. The product label also notes that the use of pioglitazone for more than one year may be associated with an increased risk of bladder cancer. The most common side effects reported by patients using pioglitazone include cold-like symptoms, headache, sinus infection, muscle pain, and sore throat.

Generic drugs approved by FDA are of the same high quality and strength as brand-name drugs. The generic manufacturing and packaging sites pass the same quality standards as those for brand-name drugs.