

Glenmark Generics gets US FDA approvals for three ANDA

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Glenmark Generic Inc., USA, a subsidiary of Glenmark Generics, has received three ANDA approvals from US FDA. It received final ANDA approvals for Indomethacin 25 mg and 50 mg capsules, USP and sulfamethoxazole and trimethoprim double and single strength tablets. These products are currently available and the company has commenced shipping from their New Jersey facility.

Indomethacin is classified as a non-steroidal antirheumatic and has been found effective in active stages of moderate to severe rheumatoid arthritis including acute flares of chronic disease, moderate to severe ankylosing spondylitis, moderate to severe osteoarthritis, acute painful shoulder (bursitis and/or tendinitis) and acute gouty arthritis. Sulfamethoxazole and trimethoprim tablets are indicated for urinary tract infections, acute otitis media, acute exacerbations of chronic bronchitis in adults, shigellosis, pneumocystis carinii pneumonia and traveler's diarrhoea in adults.

Glenmark also received tentative ANDA approval for eszopiclone, the generic version of Sepracor's Lunesta which achieved annual sales of US\$ 760 million for the 12 month period ending September 2010 according to IMS Health and is the second highest selling branded prescription medication in its class.

Earlier this, Glenmark entered into a settlement and license agreement with Sepracor to resolve a United States patent infringement suit related to Glenmark's filing an ANDA for Eszopiclone with the US FDA. Under the terms of this agreement, and upon approval and entry of Consent Judgment and Order of Permanent Injunction by the US District Court for the District of New Jersey, Glenmark would be permitted to launch its generic product on the later of November 30, 2013, which is two and one half months prior to the expiry of Sepracor's US patent.

Glenmark is currently authorized to distribute 65 products in the US. It currently has 40 ANDAs filed with US FDA pending approval and continues to rely on the strength of its internal pipeline projects as well as continuing to explore partnerships to augment the breadth of their existing portfolio.