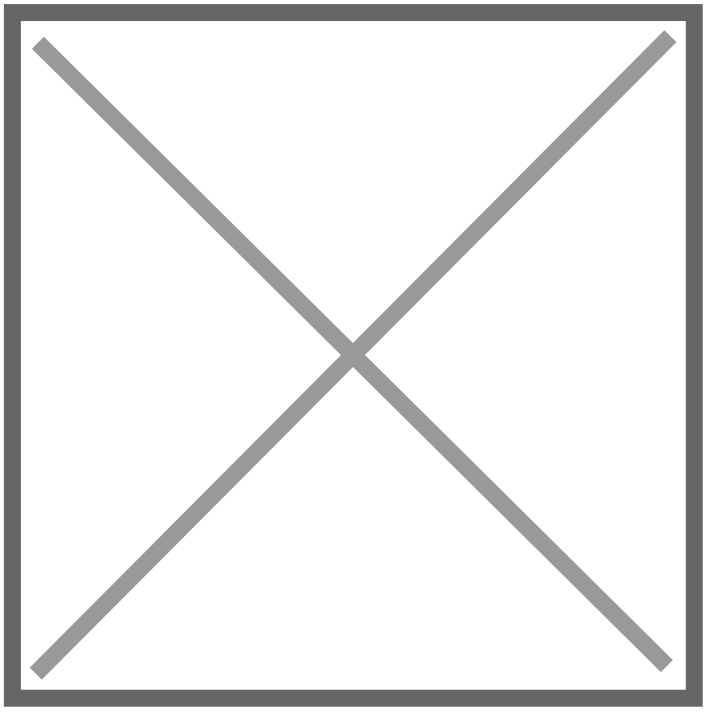
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Ranbaxy granted USA FDA approval

11 April 2003 | News



Ranbaxy Laboratories Limited (RLL), received the approval by the US Food and Drug Administration to market Amoxicillin and Clavulanate Potassium for Oral Suspension USP, 200 mg/28.5 mg (base)/5 ml and 400 mg/57 mg (base)/5 ml. The Division of Bioequivalence has determined the Ranbaxy formulations to be bioequivalent and, therefore, therapeutically equivalent to AugmentinÂ® for Oral Suspension*, 200 mg/5 ml, and 400 mg/5 ml, respectively, of GlaxoSmithKline. AugmentinÂ® has combined sales of $1.2 billion with total sales of $272.5 million in the suspension market (IMS - MAT: December 2002).

Amoxicillin and Clavulanate Potassium for Oral Suspension is indicated for the treatment of infections caused by susceptible strains of the designated organisms in the conditions like Lower Respiratory Tract Infections, Otitis Media, Sinusitis, Skin and Skin Structure Infections, and Urinary Tract Infections. While AugmentinÂ® is indicated only for these conditions listed above, infections caused by Ampicillin-susceptible organisms are also amenable to AugmentinÂ® treatment due to its Amoxicillin content. Commenting on the approval, Dipak Chattaraj, president and CEO of Ranbaxy Pharmaceuticals Inc., USA, said. "We were delighted to make yet another dosage form of Amoxicillin available based on the skills and talents that are available through our parent company, Ranbaxy Laboratories Limited. This again demonstrates our depth and breadth of expertise to add to our expanding product portfolio, along with our commitment to bring generic alternatives to the US healthcare system. We are adding yet another product that has clinical utility and value, and as such, will distinguish Ranbaxy in the years to come".

Sales and marketing for this product will be supported by the Ranbaxy Sales and Marketing Group and product will be made available to all dispensing outlets located throughout the US including chain pharmacies, wholesalers, and generic distributors as soon as inventories are achieved to support market requirements.

Ranbaxy Laboratories Limited, India's largest pharmaceutical company, manufactures and markets branded generic pharmaceuticals and Active Pharmaceutical Ingredients. Ranbaxy's continued focus on R&D has resulted in several approvals in developed markets and significant progress in New Drug Discovery Research. Ranbaxy's foray into Novel Drug Delivery Systems has led to proprietary "platform technologies" resulting in a number of products under development. The Company is selling its products in over 70 countries and has an expanding international portfolio of affiliates, joint ventures and alliances, ground operations in 25 countries and manufacturing operations in seven countries.