

Lupin receives USFDA approval for ceftriaxone sterile vials for injection_____

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Mumbai, 1 October 2003: Lupin Ltd today announced that the U.S. Food and Drug Administration (USFDA) has approved the company's abbreviated new drug application (ANDA) for ceftriaxone vials for injection 250 mg, 500 mg, 1g and 2g, the generic equivalent of Rocephin® marketed by Roche.

Lupin is the first company with an ANDA approval for ceftriaxone. It is the second injectable approval for Lupin. Lupin received ANDA approval for cefotaxime vials for injection last week. Ceftriaxone is used for urinary tract infections, lower respiratory tract infections, meningitis, skin and skin structure infections, surgical prophylaxis, intra-abdominal infections and pelvic inflammatory disease.

Lupin's CMD Dr. Desh Bandhu Gupta stated ' The approval of this important hospital drug demonstrates Lupin's capability to manufacture sterile active pharmaceutical ingredients as well as injectable finished products and our commitment to manufacture cephalosporin products.'

Lupin intends to launch the product in the US after product patent expiry in July 2005. The market size of Rocephin is US \$ 655 million (MAT June 2003) as per IMS.

This is the third ANDA approval for Lupin in this year. Lupin received FDA approval for cefuroxime axetil tablets and cefotaxime for injection earlier this year.

About Lupin

Headquartered in Mumbai, Lupin develops, manufactures and markets generic intermediates, active pharmaceutical ingredients and finished dosages. Lupin's revenue in FY2002-03 was Rs.11.2 billion on an equity base of Rs. 401 million.

Nine of Lupin's plants have been approved by the USFDA and two plants have been approved by the UKMCA.

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