Lupin receives USFDA approval for cefuroxime axetil tablets_____

Mumbai, 28 July 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 cefuroxime axetil 250mg and 500mg tablets, the AB-rated generic equivalent of GlaxoSmithKline's **Ceftin**® tablets. The product patent for the amorphous form of cefuroxime axetil will expire on 29 July 2003.

This ANDA approval is the first finished product approval for Lupin in the US market Lupin has entered into an agreement with Watson Pharmaceuticals Inc. for marketing the product in the US. The product will be manufactured at Lupin's manufacturing location at Mandideep, near Bhopal city, in India. The market size of cefuroxime axetil is estimated at US $310 million (December 2002) as per IMS.

Cefuroxime axetil is a semi-synthetic, broad-spectrum cephalosporin antibiotic for oral administration. The tablets are indicated for treating bacterial infections caused by susceptible strains of designated organisms in the pharyngitis and tonsillitis, lower respiratory tract infections, urinary tract infections,
and skin infections.

About Lupin

Headquarterd 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.

Close