

Ranbaxy files 2 NDAs in USA

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Ranbaxy Laboratories Ltd, India's largest pharmaceutical company, has filed two New Drug Applications (NDAs) in the US for Metformin and Ofloxacin during the quarter ending 31 December 2002.

According to the company's press release, Ranbaxy has, so far, filed 23 NDAs during the year 2002 and received 11 approvals taking the cumulative number of approvals to 58 with 37 pending approvals. Final approvals from the US Food and Drug Administration (FDA) to manufacture and market Amoxicillin for oral suspension USP, 200 mg/5 ml and 400 mg/5 ml, Isotretinoin, 10, 20, and 40 mg capsules and Co-amoxyclov 500mg/125mg (base) tablets were also received during the quarter ending 31 December 2002.

The release says that Ranbaxy, which is selling its products in over 70 countries, will soon receive approval for RBx 7644 (Ranbezolid), an extended spectrum Oxazolidinone from the Drugs Controller General of India, to commence Phase I clinical trials for both its oral and intravenous usage form in India. RBx 7644 (Ranbezolid) is presently undergoing Phase I clinical trials in the UK.

Commenting on the business results, DS Brar, CEO & managing director, Ranbaxy Laboratories Ltd said, "the results have been very encouraging. We have been able to significantly improve our operational effectiveness and financial performance. A sound base has been established to enter into the speciality products segment in key developed markets".