

US approves India's Ranbaxy to make generic Lipitor

December 1 2011

Indian pharmaceutical giant Ranbaxy won US regulatory approval to make the first generic version of cholesterol lowering drug Lipitor, a Pfizer product whose patent expired Wednesday.

Ranbaxy had faced delays in gaining US <u>Food and Drug Administration</u> approval due to problems with quality control at some of their Indian factories.

The FDA on Wednesday "approved the first generic version of the cholesterol-lowering drug Lipitor (atorvastatin calcium tablets)," an agency statement said.

"Ranbaxy Laboratories Ltd. has gained approval to make generic atorvastatin calcium tablets in 10 milligram, 20 mg, 40 mg, and 80 mg strengths. The drug will be manufactured by Ohm Laboratories in New Brunswick, New Jersey."

Lipitor was the best-selling drug of all-time, and earned Pfizer 100 billion dollars since coming on the market in 1997.

In the United States, anti-cholesterol drugs account for 255 million prescriptions a year, and about nine million people are taking Lipitor.

US-based Watson Pharmaceuticals earlier announced its launch of a generic version of Lipitor, atorvastatin calcium, under an exclusive supply and distribution agreement with Pfizer, whereby Pfizer



manufactures the drug and Watson sells it, sharing net sales with Pfizer until 2016.

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