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Ranbaxy gets nod for new generic BP drug

Six-month period of exclusivity to sell

OUR BUREAU

New Delhi, June 27

In a move that is likely to bring relief to Ranbaxy Laboratories, the US Food and Drugs Administration (FDA) has given its nod to the company to manufacture and market Valsartan tablets on an exclusive basis.

The drug-maker's US plant, Ohm Laboratories, received the approval from the US regulator for the generic equivalent of Diovan manufactured by Novartis, which is used to treat high blood pressure and heart failure, the company said on Friday.

Since Ranbaxy is the first company to make the generic version of Diovan, it will get a six-month period of exclusivity to sell it.

The USFDA has concluded that the new generic drug by Ranbaxy is the bioequivalent of the branded drug Diovan and has the same effects, the company said. As of April this year, the total annual market sales for Diovan stood at $2.19 billion. With this approval, the company's outlook with regard to regulatory issues with the USFDA is also looking up. Speculations about whether or not the company would get this approval were rife till recently, fuelled by a spate of regulatory actions against the company.

In fact, the patent for Diovan held by Novartis expired in September 2012, but Ranbaxy, which had the first rights to make the generic version of the medicine, was embroiled in quality concerns at its plants.

Ranbaxy, which is in the middle of a deal to be acquired by Sun Pharmaceuticals for $3.2 billion, has been on a rollercoaster ride for almost a decade with recurrent actions by the USFDA for regulatory violations such as fabrication of drug test reports and selling adulterated drugs.

In January, the USFDA issued an import alert on Ranbaxy's Toansa plant in Punjab. Currently, all its Indian plants are banned from exporting drugs to the US. The only Ranbaxy plant which does not face a ban is the US facility. Ranbaxy's scrip rose 5.38 per cent to close at ₹497 on Friday following the positive news.

Company