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## **Aurobindo gets USFDA's tentative nod for Crestor**

By PTI May 13 2010 , Mumbai

Direct link to the News/Story:-

<http://www.mydigitalfc.com/companies/aurobindo-gets-usfdas-tentative-nod-crestor-798>

Tags: Aurobindo, Crestor tablets, USFDA, Companies

Aurobindo Pharma today said it has received tentative approval of the US Food and Drug Administration (FDA) for the generic version of Crestor tablets used in the cardiovascular therapeutic area.

The company has received the approval for Rosuvastatin tablets, which is generic version of US-based pharmaceutical firm IPR Inc, in 5mg, 10mg, 20mg and 40 mg strength, Aurobindo Pharma said in a filing to the Bombay Stock Exchange (BSE).

The company said it has filed the abbreviated new drug application (ANDA) with FDA with Paragraph IV certification with first to file status.

Paragraph IV certification with first to file status, gives generic firm an opportunity to launch the drug in the US with a exclusive marketing rights of up to 180 days.

The company is currently facing litigation related to its drug application in the US District Court of Dilaware alleging patent infringements.

The total market for the drug in the US is around USD 2.9 billion, according to market research firm Newport, the company said.

With this, the total number of ANDA approvals with Aurobindo has gone up to 116, including 86 final approvals and 30 tentative approvals.