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Jubilant receives approval for 2 generic drugs

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Jubilant receives approval for 2 generic drug versions from USFDA

Jubilant Life Sciences has received Abbreviated New Drug Application (ANDA) final approval from the US Food and Drug Administration (US FDA) for Mycophenolate Mofetil USP, 250 mg Capsules and 500 mg Tablets (from its US subsidiary, Jubilant Cadista Pharmaceuticals Inc.) and Rizatriptan Tablets 5 mg and 10 mg (from its Indian subsidiary, Jubilant Generics Ltd.).

Mycophenolate Mofetil USP, 250 mg Capsules and 500 mg Tablets is the generic version of Cellcept (of Roche), an immunosuppressant which is used to help prevent organ rejection in transplants. The current annualized US market size for Mycophenolate Mofetil USP, 250 mg Capsules and 500 mg Tablets as per IMS is $245 Million.

Rizatriptan Tablets 5 mg and 10 mg is the generic version of Maxalt (of Merck), used for the treatment of migraine. The current annualized US market size for Rizatriptan Tablets 5 mg and 10 mg as per IMS is $70 Million.

As on September 30, 2014, Jubilant Life Sciences had a total of 781 filings for formulations of which 322 have been approved in various regions globally. This includes 72 ANDAs filed in the US and 46 Dossier filings in Europe.