

Natco Pharma files NDA with USFDA

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Natco Pharma has filed Abbreviated New Drug Applications (ANDAs) for fingolimod capsules and cabazitaxel injection with the US Food and Drug Administration (US FDA).

"Natco and its associated marketing partners for the above products in the US, believe that they are the first company to have filed a substantially complete ANDA which includes a paragraph IV certification for Fingolimod capsules and Cabazitaxel injection, providing 180 days of marketing exclusivity upon its final USFDA approval," the company said in a filing to BSE.

Fingolimod is a generic version of Novartis' Gilenya and is used for the treatment of multiple sclerosis. Cabazitaxel, a generic of Sanofi's Jevtana, is indicated for the treatment of hormone-refractory prostate cancer. Once approved, the company expects to get 180 days of marketing exclusivity for these products.