

Strides Shasun's generic Ibuprofen receives USFDA approval

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Drug firm Strides Shasun has received approval from the US health regulator for generic Ibuprofen capsules, 200 mg, used for relieving pain.

The company's wholly-owned subsidiary Strides Pharma Global has received approval for Ibuprofen capsules in the strength of 200 mg from the United States Food & Drug Administration (USFDA).

The company's product is a generic version of Pfizer Inc's Advil Liqui-Gels 200 mg.

"With a focus to secure its API supply chain for the product, the company under prior approval supplements filing will apply for a source change to Solara Active Pharma Sciences, a group company having a leading API franchise," Strides Shasun said.

The product will be commercialised in Q4 of FY19 post completion of API source change process. The product will be manufactured at the company's oral dosage facility in Bangalore.

The company has 74 cumulative abbreviated new drug application (ANDA) filings with USFDA of which 45 ANDAs have been approved as of date and 29 are pending approval.