Zydus receives final approval from USFDA for Ibuprofen and Famotidine Tablets, 800 mg/26.6 mg

Ahmedabad, India, 22 February, 2025

Zydus Lifesciences Limited (including its subsidiaries/ affiliates, hereafter referred to as "Zydus") has received final approval from the United States Food and Drug Administration (USFDA) to manufacture Ibuprofen and Famotidine tablets, 800 mg/26.6 mg. (USRLD: Duexis Tablets, 800 mg/26.6 mg).

Ibuprofen and famotidine combination is indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers (gastric and/or duodenal ulcers), in patients who are taking ibuprofen for those indications. Ibuprofen and famotidine tablets will be produced at Zydus Lifesciences Ltd (SEZ), Ahmedabad.

Ibuprofen and Famotidine tablets had annual sales of USD 3.6 mn in the United States (IQVIA MAT December 2024).

The group now has 415 approvals and has so far filed 483* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 31st December 2024)*

PRESS RELEASE

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