Zydus receives final approval from USFDA and 180 days CGT exclusivity for Finasteride and Tadalafil Cap Capsules

Ahmedabad, India, 16 March, 2024

Zydus Lifesciences Limited's (formerly known as Cadila Healthcare Limited) has received final approval from the United States Food and Drug Administration (USFDA) to market Finasteride and Tadalafil Capsules USP 5 mg/5 mg. (USRLD: ENTADFI ™).

Zydus is the "first approved applicant" for Finasteride and Tadalafil Capsules, 5 mg/5 mg, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act and therefore is eligible for 180 days of CGT exclusivity. Finasteride and Tadalafil is used to treat benign prostatic hyperplasia. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ II, India.

The group now has 392 approvals and has so far filed over 460* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 31st December 2023)*

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PRESS RELEASE

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