Zydus receives final approval from USFDA for Fludrocortisone Acetate Tablets USP, 0.1 mg

Ahmedabad, India, 17 October, 2024

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 Fludrocortisone Acetate Tablets USP, 0.1 mg (USRLD: Florinef Tablets, 0.1 mg).

Fludrocortisone acetate tablets are indicated as partial replacement therapy for primary and secondary adrenocortical insufficiency in Addison's disease and for the treatment of salt-losing adrenogenital syndrome. Fludrocortisone acetate tablets will be produced at the Group's manufacturing site at Moraiya, Ahmedabad.

Fludrocortisone acetate tablets had annual sales of USD 19.9 mn in the United States (IQVIA MAT July 2024).

The group now has 400 approvals and has so far filed over 465* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 30th June 2024)*

PRESS RELEASE

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