Zydus receives final approval from the USFDA for Zinc Sulfate Injection USP, 10 mg/10 mL (1 mg/mL), 30 mg/10 mL (3 mg/mL), and 25 mg/5 mL (5 mg/mL) Pharmacy Bulk Package Vials

Ahmedabad, India, 24 August, 2023

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) for Zinc Sulfate Injection USP, 10 mg/10 mL (1 mg/mL), 30 mg/10 mL (3 mg/mL), and 25 mg/5 mL (5 mg/mL) Pharmacy Bulk Package Vials (USRLD: Zinc Sulfate Injection USP, 10 mg/10 mL (1 mg/mL), 30 mg/10 mL (3 mg/mL), and 25 mg/5 mL (5 mg/mL)).

Zinc Sulfate Injection is indicated in adult and paediatric patients as a source of zinc for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated. The drug will be manufactured at the group's formulation manufacturing facility at Jarod.

Zinc Sulfate Injection USP, 10 mg/10 mL (1 mg/mL), 30 mg/10 mL (3 mg/mL), and 25 mg/5 mL (5 mg/mL) Pharmacy Bulk Package Vials had annual sales of USD 17.1 mn in the United States (IQVIA MAT June 2023).

The group now has 377 approvals and has so far filed over 444* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 30th June 2023)

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PRESS RELEASE

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