Zydus announces final approval from the USFDA for Ascorbic Acid Injection with 180-Days CGT exclusivity

Ahmedabad, India, 21 August 2026

Zydus Lifesciences Limited (Zydus) announces the receipt of final approval from the United States Food and Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Ascorbic Acid Injection USP, 25,000 mg/50 mL (500 mg/mL), 5,000 mg/10 mL (500 mg/mL). The product is primarily used for the short-term treatment of scurvy in adult and paediatric patients age 5 months and older for whom oral administration is not possible, insufficient or contraindicated.

Zydus' Ascorbic Acid Injection is the generic equivalent of the reference listed drug (RLD), Ascor® Injection, 25,000 mg/50 mL (500 mg/mL). The USFDA has designated the ANDA for the product as a Competitive Generic Therapy (CGT).Eligibility for the 180-day exclusivity available to certain competitive generic therapies is determined by the USFDA and, where applicable, the period runs from the date of first day of commercial marketing of the product.

The product will be manufactured at the group's USFDA-approved injectable manufacturing plant at Jarod, near Vadodara in Gujarat, and will be marketed in the US market by Zydus Pharmaceuticals (USA) Inc.

The brand product had annual sales of approximately USD 11.6 mn in the United States. (IQVIA MAT June-2026).

The Group now has 448 approvals and has so far filed 513* ANDA with the USFDA. *(*As on 30-June-2026)*

PRESS RELEASE

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