

Glenmark Generics gets ANDA approval for lateral sclerosis drug

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Glenmark Generics USA based subsidiary of Glenmark Generics Limited has been granted final abbreviated new drug approval (ANDA) from the United States Food and Drug Administration (U.S. FDA) for Riluzole Tablets, 50mg. Glenmark is set to commence shipping immediately.

Riluzole is indicated for the treatment of amyotrophic lateral sclerosis. Based on IMS Health sales data for the 12 month period ending March 2013, Riluzole garnered sales of USD 64 million.

Glenmark's current portfolio consists of 86 products authorized for distribution in the US marketplace and 52 ANDA's pending approval with the U.S. FDA. In addition to these internal filings, GGI continues to identify and explore external development partnerships to supplement and accelerate the growth of the existing pipeline and portfolio.