Zydus Cadila gets USFDA final approval for Mesalamine Delayed-Release Tablets USP, 1.2 g

The product will be manufactured at the Moraiya manufacturing facility for the US market

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Ahmedabad, June 7, 2017

Zydus Cadila has informed that the USFDA has given final approval to market Mesalamine Delayed- Release Tablets USP, 1.2 g in the US market. Zydus Cadila was the first to file an Abbreviated New Drug Application (ANDA) for a generic version of Lialda® (mesalamine).

Lialda® is indicated for the treatment of mild to moderate ulcerative colitis. Ulcerative colitis is a chronic inflammatory bowel disease that affects approximately 700,000 people in the United States. The generic version of Lialda® (mesalamine) will be produced at Moraiya Plant located at Ahmedabad. The estimated brand sales for Mesalamine Delayed-Release Tablets USP, 1.2 g is US $ 1.145 billion as per IMS MAT April 2017.

The group now has more than 115 approvals and has so far filed over 300 ANDAs since the commencement of the filing process in FY 2003-04.

About Zydus Cadila

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies. The group employs over 20000 people worldwide and is dedicated to creating healthier communities globally. Zydus aspires to be a research-based pharmaceutical company by 2020.