Press Release

Zydus Cadila receives final approval from USFDA for Dimethyl Fumarate Delayed-Release Capsules

Ahmedabad, 25 September, 2020

Zydus Cadila has received final approval from the USFDA to market Dimethyl Fumarate Delayed-Release Capsules, (US RLD: Tecfidera®) in the strengths of 120 mg and 240 mg. In its approval, the USFDA noted that Zydus was one of the first ANDA applicants to submit a substantially complete ANDA and is therefore eligible for 180 days of generic drug exclusivity along with other first ANDA applicants.

The USFDA granted approval following entry of judgment in favor of Zydus Cadila and other ANDA applicants by the United States District Court for the District of Delaware, holding that the only unexpired patent covering Tecfidera® is invalid.

Dimethyl Fumarate Delayed-Release Capsules are indicated for the treatment of patients with relapsing forms of multiple sclerosis and will be manufactured at the group's manufacturing facility at the SEZ, Matoda.

The group now has 303 approvals and has so far filed over 390 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 nearly 25000 people worldwide and is dedicated to creating healthier communities globally.

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