



Innovating for  
affordable healthcare

# Shilpa Medicare Limited

**Manufacturers and Exporters of Bulk Drugs**

Shilpa House # 12-6-214/A-1, Hyderabad Road,

RAICHUR - 584 135, Karnataka, India.

Phone : +91-8532-238704, Fax : +91-8532-238876

E-mail : [info@vbsilpa.com](mailto:info@vbsilpa.com) Website : <http://www.vbsilpa.com>

CIN No. L85110KA1987PLC008739

Dated: 16<sup>th</sup> November, 2018

Corporate Relationship Department,  
BSE Limited  
Phiroze Jeejeebhoy Towers,  
Dalal Street, Fort,  
Mumbai-400 001

National Stock Exchange of India Limited  
Exchange Plaza, 5<sup>th</sup> Floor,  
Plot No.C/1, G Block  
Bandra Kurla Complex, Bandra (E)  
Mumbai-400 051

Dear Sir/Madam,

**Sub: Intimation under regulation 30 of the SEBI (LODR) Regulations- Reg.**  
**Ref: Stock Code: NSE: SHILPAMED/BSE-530549**

\*\*\*\*\*

This is to inform you that the Company's ANDA (#210291) for Dimethyl Fumarate Delayed Release Capsules 120 mg & 240 mg has been granted tentative approval by FDA.

Dimethyl Fumarate Delayed Release Capsules 120 mg & 240 mg is a generic of TECFIDERA, used in the treatment of patients with relapsing forms of multiple sclerosis.

This ANDA is a first to file submission made on NCE-1 dated March 27, 2017. FDA review process was completed and got approval within a period of 19.5 months from the date of submission.

According to IQVIA MAT Q2 2018 data, the US market for Dimethyl Fumarate DR Capsules is approximately US\$ 3.46 billion.

This is for your information and doing the needful.

With Regards,

For **SHILPA MEDICARE LIMITED**

  
**MADHUSUDHAN REDDY**  
Company Secretary &  
Compliance Officer

