Innovating for affordable healthcare

Shilpa Medicare Limited

Corporate & Admin Office :

"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur-584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Dated: 18th February, 2021

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

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

Dear Sir/Madam,

Sub: Investors Notification u/r 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations 2015.

Ref: Stock Code: NSE: SHILPAMED/BSE-530549

Please find herewith attached investors notification on information about receipt of Import alert 66-40.

This is for your information and records.

With Regards,

For SHILPA MEDICARE LIMITED

V. V. Krishna Chaitanya

SHILPA MEDICARE LTD. RAICHUR

V V Krishna Chaitanya
Company Secretary

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INVESTOR NOTIFICATION

To, **February 18, 2021**
Our Valued Investors.
Sub: Information about receipt of Import Alert 66-40
Dear Sir/Madam,

Further to our Letter dated October 10, 2020, (informing about receipt of Warning Letter), we wish to inform you that the Company has received an Import Alert 66-40 on February 17, 2021, pursuant to the USFDA inspection of the Unit IV, Jadcherla, Telangana facility from Feb 13 – 20 and Feb 24-25, 2020.

We also wish to inform you that three products have been exempted from the Import Alert – Azacitidine for Injection, Cyclophosphamide Capsules and Erlotinib Tablets, subject to certain conditions viz. 3 rd. Party Certification, no OOS/breach of sterility, triplicate testing and concurrent stability for first three batches. Please note that USFDA exempted formulation sales are our largest revenue source.

(Rs.in Lakhs)

Year	2020-21-As on Dec'20	2019-20	2018-19
Total Formulations Sales	16240	19436	17104
Exempted Formulation sales*	13962	13426	14467
%	86	69	85

* includes all products permitted for sales in the US

Exempted Formulations Sales **(Rs. In lakhs)**

Continent	2020-21-As on Dec'20	%	2019-20	%	2018-19	%
USA	6106	**44**	13280	**99**	14387	**99**
Europe & others	7856	**56**	146	**01**	80	**01**
Total	13962	**100**	13426	**100**	14467	**100**

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We had received fifteen 483 observations at the closeout of FDA inspection on February 25, 2020. The Warning Letter received on 10 Oct 2020 had specifically mentioned two citations – (i) inadequate handling of OOS and (ii) inadequate handling of market complaints, including failure to file FAR within stipulated time.

We had responded to the Warning Letter on October 30, 2020, followed by three follow-up responses outlining the CAPA's and their progress. We have had two tele-meetings with the USFDA on Nov 12, 2020 and 25 Nov, 2020. We have not received any subsequent communication from USFDA since Nov 25, 2020, until yesterday.

This notification of Import Alert does not mention any further reasons/observations other than nonconformance to cGMP.

We have already engaged the services of US based reputed GMP 3rd Party Consultants to help us with the remediation efforts.

We are committed to addressing the concerns raised by the USFDA and will work with the USFDA to resolve these issues at the earliest. We uphold quality and compliance with utmost importance and are committed to maintaining cGMP and quality standards across all Shilpa facilities.

The Notification on Import Alert received from the USFDA, is enclosed herewith.

We shall keep you informed on further significant developments, including supply related information.

Thanking you,

Yours faithfully,

For Shilpa Medicare Limited

V V Krishna Chaitanya
Company Secretary

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

February 17, 2021

Mr. Vishnukant Chaturbhuj Bhutada
Managing Director
Shilpa Medicare Limited
#12-6-214/A1
Hyderabad Road, Raichur – 584135
Karnataka
India

Reference: FEI 3009876430

Dear Mr. Bhutada:

The United States Food and Drug Administration (FDA) has reviewed the Form FDA 483, establishment inspection report (EIR), and your response to the Form FDA 483 pertaining to the inspection conducted at Shilpa Medicare Limited, Unit-IV, at Plot No. S-20 to S-26, Pharm, Formulation SEZ, TSIIC, Green Industrial Park, Polepally (Village), Jadcherla (Mandal), District Mahabubnagar (Telangana), from February 13 to 20, 2020, and February 24 to 25, 2020.

We have determined from our review of the cited deficiencies that all drugs manufactured at this facility, except Azacitidine for injection, Erlotinib tablets, and Cyclophosphamide capsules, are subject to refusal of admission pursuant to section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not appear to conform to current good manufacturing practice (CGMP) within the meaning of section 501(a)(2)(B) of the FD&C Act.

Your firm is listed under Import Alert 66-40, whereby all future shipments of drugs, except Azacitidine for injection, Erlotinib tablets, and Cyclophosphamide capsules, that originate from your facility may be refused admission into the United States (U.S.) until your firm can demonstrate the drugs manufactured at this site, and intended for the U.S. market, are in compliance with CGMP.

Due to potential shortage implications and/or medical necessity of certain drug products, exceptions to the import alert have been made for the following finished products: Azacitidine for injection, Erlotinib tablets, and Cyclophosphamide capsules. This exception will be reconsidered if shortage and/or medical necessity implications change.

The following recommendations should be met for all batches of Azacitidine for injection, Erlotinib tablets, and Cyclophosphamide capsules produced at your facility and excluded from Import Alert 66-40 given the violations cited in Warning Letter No. 320- 20-01, dated October 9, 2019:

1. All batches to be released should be certified by an independent third party auditor. The certificate must indicate the date the batch was released by the Shilpa Medicate Limited Quality Unit and certified by the independent third party.

2. None of the batches should be involved in an out-of-specification/failure or breach on sterility assurance. Any quality defect or breach in sterility assurance found during the third party certification must be notified to the FDA immediately.

3. Each batch should be tested in triplicate and meet the appropriate quality standards prior to its release for distribution.

4. For each of the three products in carve out, the first three batches should be added to Shilpa stability program.

It remains your responsibility to manufacture all products in conformance to CGMPs and to initiate appropriate market action should you become aware that a batch has failed to meet its quality standard after distribution.

If you have questions or concerns regarding this letter, contact Rafael E. Arroyo, Compliance Officer, at the address and e-mail below.

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Manufacturing Quality
Division of Drug Quality I
White Oak, Building 51 Room 4235
10903 New Hampshire Avenue
Silver Spring, MD 20993
E-mail: CDER-OC-OMQ-Communications@fda.hhs.gov

Sincerely,

Carmelo R. Rosa -S

Carmelo Rosa, Psy.D.
Director, Division of Drug Quality I
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research