BEFORE THE ADJUDICATING OFFICER
SECURITIES AND EXCHANGE BOARD OF INDIA

[ADJUDICATION ORDER: Order/DS/RK/2022-23/17569]

UNDER SECTION 23 I (2) OF SECURITIES CONTRACTS (REGULATION) ACT, 1956 AND RULE 5 OF SECURITIES CONTRACTS (REGULATION) (PROCEDURE FOR HOLDING INQUIRY AND IMPOSING PENALTIES) RULES, 2005

In respect of –

Shilpa Medicare Limited
PAN AADCS8788F
Address:
Shilpa House, 12-6-214/ A1,
Hyderabad Road, Raichur,
Karnataka - 584135
info@vbshilpa.com/ cs@vbshilpa.com

BRIEF BACKGROUND

1. The Securities and Exchange Board of India (hereinafter, referred to as "**SEBI**") carried out investigation into whether the disclosures made by Shilpa Medicare Limited (hereinafter, referred to as "**the company/ Noticee**") in connection with the Warning Letter and Import Alert issued by the United States Food and Drug Administration (hereinafter, referred to as "**USFDA**") were in compliance with the requirements prescribed under the Securities Contracts (Regulation) Act, 1956 (hereinafter, referred to as "**SCR Act, 1956**") and the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 (hereinafter, referred to as "**LODR Regulations, 2015**")

APPOINTMENT OF ADJUDICATING OFFICER

2. I have been appointed as the Adjudicating Officer vide communique dated December 07, 2021 under the Section 23 I of SCR Act, 1956 read with Rule 3 of

Securities Contracts (Regulation) (Procedure for Holding Inquiry and Imposing Penalties) Rules, 2005 (hereinafter, referred to as "**Adjudication Rules**") to inquire into and adjudge under the provisions of Section 23E of the SCR Act, 1956 for the alleged violation of Section 21 of the SCR Act, 1956 read with clause 2 (i) of the Listing Agreement and Regulation 4 (1) (d) and Regulation 30 (1) of the LODR Regulations, 2015 read with Clause 8 of para B of Part A of Schedule III of LODR Regulations, 2015 by the Noticee.

SHOW CAUSE NOTICE, REPLY AND HEARING

3. A Show Cause Notice (hereinafter, referred to as "**SCN**") dated December 28, 2021 was issued to the Noticee. The following documents were enclosed as annexures to the SCN.

Annexures to SCN	
Annexure	**Particulars**
A	Copy of the communiqué dated December 07, 2021, communicating the appointment of the Adjudicating Officer.
B	Noticee's disclosure dated October 10, 2020 to the Exchanges, BSE Limited and National Stock Exchange of India Limited.
C	Warning letter dated October 09, 2020 received from USFDA.
D	Import Alert from the USFDA dated February 17, 2021.
E	Noticee's letter to the Exchanges dated February 18, 2021.
F	Investor Notification dated February 18, 2021 under Regulation 30 of the LODR Regulations, 2015 issued by the Noticee.
G	Noticee's letter dated March 25, 2021.

4. The main observations and allegations against the Noticee raised in the SCN are as under:

(a) Noticee vide disclosure dated October 10, 2020 disclosed to BSE Limited (hereinafter, referred to as "**BSE**") & National Stock Exchange of India Limited (hereinafter, referred to as, "**NSE**") that it had received a Warning Letter dated October 09, 2020 through email from the USFDA for its Jadcherla facility in Telangana. However, the letter dated October 09, 2020 itself was not disclosed along with the Noticee's disclosure made on October 10, 2020.

(b) On perusal of the USFDA's Warning Letter dated October 09, 2020, it is observed that the letter gives the background of the Warning Letter, the various reasons for which warning has been issued and the possible repercussions if the violations are not corrected by the Noticee. However, the disclosure neither contains any reason or background for the issuance of the Warning Letter nor its impact.

(c) It was observed from the website of BSE that the price of the scrip dipped by 8.6 % on the next market opening day of disclosure (i.e. October 12, 2020) from the previous closing price (i.e. on October 09, 2020) following the said disclosures that were made on October 10, 2020.

(d) The Warning Letter issued by the USFDA amounts to regulatory action which ought to have been disclosed. It is alleged that the Noticee failed to disclose the information pertaining to the regulatory action with impact thereby violating Clause 8 of Para B of Part A of Schedule III of the LODR Regulations, 2015.

(e) The disclosure dated October 10, 2020 made by the Noticee, although timely, was not adequate thereby failing to comply with Regulation 4(1)(d) of the LODR Regulations, 2015. Furthermore, it was alleged that the factum of inspection and possible repercussions in the event the violations are not corrected were material in nature, and that the Noticee failed to disclose such material information thereby failing to comply with Regulation 30 (1) of the LODR Regulations, 2015.

(f) In view of the foregoing, it was alleged that the Noticee had violated Section 21 of the SCR Act, 1956 read with clause 2 (i) of the Listing Agreement and Regulation 4 (1) (d) and Regulation 30 (1) of the LODR Regulations, 2015 read with Clause 8 of para B of Part A of Schedule III of LODR Regulations, 2015.

5. The SCN was served on the Noticee through Speed Post on January 03, 2022. The Noticee's reply to the SCN, a digitally signed letter dated January 18, 2022 was received through email on the same day. An opportunity of hearing was given to the Noticee on March 03, 2022 which was communicated vide letter

dated January 31, 2022. The Noticee's authorized representatives appeared for the hearing on March 03, 2022 and made their submissions.

6. In its reply, while denying the allegations the Noticee has contended as under:

   (a) Of its three facilities, only the Jadcherla unit is under Import Alert from the USFDA. The facility was and continues to be approved by the European regulator and other regulators.

   (b) As per the available statistics, in the year 2020, the regulatory agency USFDA issued 15 warning letters to all of the corporations / companies in India and in the year 2019, the warning letters were issued to 23 companies in India. Receipt of such letters from USDFA during the course of regular audit is not unusual in Pharma sector.

   (c) The company has made the disclosure regarding the receipt of warning letter from USFDA in a timely manner with adequate information regarding the inspection done at the Jadcherla facility. The Noticee also stated in its disclosure that it is engaging with the USFDA and is fully committed in resolving the issue at the earliest, and that there will be minimum impact of disruption of supplies and the existing revenues from operations of the facility. Hence, in the Noticee's opinion, reproducing the entire letter or explaining repercussions in the disclosure was needless and not material.

   (d) The Warning Letter is a public document which could be accessed by anyone on the official website of the USFDA.

   (e) While making the disclosure, Noticee has looked at the industry practice and that its disclosure has been in-line with the practice generally followed the industry at large.

CONSIDERATION OF ISSUES AND FINDINGS

7. Based on the SCN, reply of the Noticee and the material available on record, the following issues arise for consideration:

I. *Whether the Noticee has violated Section 21 of the SCR Act, 1956 read with clause 2 (i) of the Listing Agreement and Regulation 4 (1) (d) and Regulation 30 (1) of the LODR Regulations, 2015 read with clause 8 of para B of Part A of Schedule III of LODR Regulations, 2015?*

II. *Does the violation, if any, by the Noticee attract monetary penalty under Section 23E of SCR Act?*

III. *If so, what should be the monetary penalty that can be imposed taking into consideration the factors mentioned in Section 23J of SCR Act?*

8. At this juncture, it is relevant to note the provisions of law applicable to the present proceeding.

(a) Section 21 of the SCR Act, 1956 is as under:

> ***Conditions for listing.***
> **21.** *Where securities are listed on the application of any person in any recognised stock exchange, such person shall comply with the conditions of the listing agreement with that stock exchange.*

(b) Provisions of the LODR Regulations, 2015 are as under:

> ***Principles governing disclosures and obligations.***
> **4.** (*1) The listed entity which has listed securities shall make disclosures and abide by its obligations under these regulations, in accordance with the following principles:*
> …
> *(d) The listed entity shall provide adequate and timely information to recognised stock exchange(s) and investors.*
>
> ***Disclosure of events or information.***
> **30.** *(1) Every listed entity shall make disclosures of any events or information which, in the opinion of the board of directors of the listed company, is material.*

(c) Clause 8 of Para B of Part A of Schedule III of the LODR Regulations, 2015 is as under:

> **B. Events which shall be disclosed upon application of the guidelines for materiality referred sub-regulation (4) of regulation (30):**
> …
> *8. Litigation(s) / dispute(s) / regulatory action(s) with impact.*

Issue No. I: Whether the Noticee has violated Section 21 of the SCR Act, 1956 read with clause 2 (i) of the Listing Agreement and Regulation 4 (1) (d) and Regulation 30 (1) of the LODR Regulations, 2015 read with clause 8 of para B of Part A of Schedule III of LODR Regulations, 2015?

9. Upon perusal of the USFDA's warning letter dated October 09, 2020, I note that the letter gives the background of the warning letter, the various reasons for which warning has been issued and the possible repercussions if the violations are not corrected by the Noticee. Relevant extract of the said warning letter dated October 09, 2020 is reproduced as under

> *"The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility at Shilpa Medicare Limited … Jadcherla (Mandal), District Mahabubnagar (Telangana), from February 13 to 20, 2020, and February 24 to 25, 2020.*
>
> *This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations (CFR), parts 210 and 211 (21 CFR parts 210 and 211)*
>
> *Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501 (a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD & C Act), 21 U.S.C. 351 (a)(2)(B).*
>
> *In addition, the inspection revealed that your firm failed to submit an NDA Field Alert Report (FAR) to FDA within three working days of receipt of information concerning significant chemical, physical, or other change or deterioration in a distributed drug product, as required by section 505 (k) of the FD & C Act, 21 U.S.C. 355 (k) and stipulated by the regulation 21 CFR 314.81(b)(1)(ii).*
> *…*
> *…*
> *…*
>
> *Conclusion*
>
> *The violations cited in this letter are not intended to be an all – inclusive list of violations that exist at your facility. You are responsible for investigating and determining the causes of these violations and for preventing their recurrence or the occurrence of other violations.*
> *…*

Until you correct all violations completely and we confirm your compliance with CGMP, FDA may withhold approval of any new drug applications or supplements listing your firm as a drug manufacturer.

Failure to correct these violations may also result in the FDA refusing admission of articles manufactured at Plot No. S-20 to S – 26, Pharm, Formulation SEZ, TSIIC, Green Industrial Park, Polepally (Village), Jadcherla (Mandal), District Mahabubnagar (Telangana), India into the United States under section 801 (a)(3) of the FD & C Act, 21 U.S.C. 381 (a)(3). Articles under this authority may be subject to refusal of admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501 (a)(2)(B) of the FD&C Act, 21 U.S.C. 351 (a)(2)(B).”

10. From the aforesaid letter dated October 09, 2020, I note the following:

(a) The warning letter was issued by USFDA based on its inspection of the Noticee’s drug manufacturing facility at Jadcherla, Telangana.

(b) The warning letter summarized ‘significant violations’ of current good manufacturing practice ((hereinafter, referred to as “**CGMP**”) regulations,

(c) The warning letter stated that as the methods, facilities, or controls for manufacturing etc., do not conform to CGMP, the Noticee’s drug products are adulterated.

(d) The response of the Noticee was inadequate,

(e) Until the Noticee corrected all the violations completely and till the USFDA confirmed the Noticee’s compliance with CGMP, the USFDA may withhold approval of any new drug applications or supplements listing the Noticee as a drug manufacturer,

(f) Failure to correct the violations may result in the USFDA refusing admission of articles manufactured at the Noticee’s Jadcherla facility.

11. The contents of the Noticee’s disclosure to the Exchanges, BSE and NSE dated October 10, 2020 areas under:

“This is to inform that the Company, has received a warning letter yesterday i.e. on 9th October 2020 at 10:06 PM (India Time) through email from the USFDA for its Jadcherla facility, Telangana.

We will be engaging with the agency and are fully committed in resolving this issue at the earliest. The Company is also committed in maintaining the

highest standards of compliances and quality manufacturing across all its facilities.

The Company believes that the warning letter will have minimum impact of disruption of supplies and the existing revenues from operations of this facility.

Shilpa Medicare Ltd. currently has three manufacturing facilities approved by USFDA – One formulation facility and two API facilties. None of these facilities except Jadcherla has any outstanding issues with the USFDA at this point of time."

12. The SCN had alleged that the said letter dated October 09, 2020 of USFDA itself was not disclosed along with the Noticee's disclosure. Further, the disclosure by the Noticee neither contained any reason or background for the issuance of the warning letter nor the impact of the warning letter.

13. The Noticee in its reply has submitted that it disclosed the receipt of the Warning Letter from USFDA in a timely manner with adequate information regarding the inspection done at its Jadcherla facility. The Noticee also stated that in its disclosure, it disclosed that it is engaging with the USFDA and is fully committed in resolving the issue at the earliest, and that there will be minimum impact of disruption of supplies and the existing revenues from the operations of this facility. Furthermore, the Noticee has submitted that the Warning Letter is a public document which could be accessed on the official website of USFDA. The Noticee in its reply has also submitted that receipt of such letters from USFDA during the course of regular audit is not unusual in Pharma sector.

14. I note that on February 17, 2021, the Noticee received an Import Alert from the USFDA. The letter received by the Noticee stated that the Noticee has been listed under Import Alert 66-40, whereby all future shipments of drugs except Azacitidie for injection Erlotinib tablets and Cyclophosphamide capsules, that originate from the Noticee's facility may be refused admission into the United States until the Noticee can demonstrate that the drugs manufactured at this site, and intended for the U.S. market, are in compliance with current good manufacturing practice. The letter dated February 17, 2021 was disclosed by the Noticee to the Exchanges, BSE and NSE vide disclosure dated February

18, 2021. The said disclosure contains the background of the Import Alert issued by the USFDA stating that it was issued pursuant to inspection of its facilities during the month of February 2020. The Noticee also issued an Investor Notification dated February 18, 2021 under Regulation 30 of the LODR Regulations, 2015 and the same was also disclosed to the Exchanges. The said Investor Notification contained the details of the Import Alert, its impact on the sales/ supply/ revenue of its products along with a copy of the said Import Alert.

15. The Noticee has submitted that there were two types of intimation by USFDA to the Noticee during the course of its regular audit, one is the advisory in nature through issue of Warning Letter dated October 09, 2021 and the other one is the regulatory action through imposition of import alert dated February 17, 2021. The Noticee, in its reply has stated that it has promptly made both the disclosures to the stock exchanges in a timely manner with adequate information considering the seriousness of the USFDA intimations. Since there was no regulatory action taken by the said authority upon the issuance of warning letter, it was felt needless to state the impact or possible repercussions which would occur if the concerns were not addressed. On the other hand when it received the import alert, the Noticee had made a disclosure along with the possible repercussions on February 18, 2021 stating that an import alert has been received from USFDA and three products i.e., Azacitidine for injection, Cyclophosphamide Capsules and Erlotinib Tablets have been exempted from the said alert. An investor notification in this regard was also made to the stock exchanges, intimating clearly the background, impact and steps taken to address the issues of the said alert.

16. I note that in order to ensure fairness and efficiency in the market, two factors generally apply: (a) Timely disclosure of relevant information by listed companies to investors and (b) Adequacy of the information disclosed. I note that Regulation 4(1)(d) of the LODR Regulations, 2005 states that the listed entity shall provide adequate and timely information to the recognised stock exchange(s) and investors. The term “information” in the aforesaid Regulation is qualified by the terms “adequate” and “timely”.

17. The SCN has alleged that the disclosure dated October 10, 2020 by the Noticee, although timely, was not adequate thereby failing to comply with Regulation 4(1)(d) of the LODR Regulations, 2015.

18. I note that while the timely dissemination of an event/information is essential, the adequacy of the information disseminated determines the usefulness of the information disclosed. The *Black's Law Dictionary* (38, 6th ed. 1990) defines "adequate" as sufficient, commensurate; equally efficient, equal to what is required, suitable to the case or occasion; satisfactory.

19. The Hon'ble Securities Appellate Tribunal in ***M/s Coimbatore Flavors & Fragrances Ltd. & Ors* v. *SEBI*** (Appeal no. 209 of 2014) observed that "*true and timely disclosures by a company or its promoters are very essential from two angles. Firstly; investors can take a more informed decision to invest or not to invest in a particular scrip secondly; the Regulator can properly monitor the transactions in the capital market to effectively regulate the same.*"

20. I note that the aforesaid contents of the Warning Letter dated October 09, 2020 were critical for the investors to take an informed decision to invest or not to invest in the scrip of the Noticee. Further, the contention of the Noticee that the Warning Letter dated October 09, 2020 was available on the website of the USFDA itself cannot be reason for not making adequate disclosure on the Stock Exchanges. It is obligatory on the part of the Noticee to make complete and adequate disclosures on Stock Exchanges where its shares are listed. Keeping the above in view, I find that the disclosure by the Noticee was not sufficient/ commensurate to meet the requirement of adequacy laid down in Regulation 4(1)(d) of the LODR Regulations, 2005.

21. The Noticee, in its reply, has relied on Chapter 4 and 10 of the "Regulatory Procedures Manual" of the USFDA (hereinafter, referred to as "**USFDA Manual**") to state that the warning letters are issued by the USFDA only as a guidance for individuals and firms to correct their practices before any enforcement action is initiated. The relevant paragraphs of the USFDA Manual relied on by the Noticee are as under:

Para 4-1-1:

> *"When it is consistent with the public protection responsibilities of the agency and depending on the nature of the violation, it is the Food and Drug Administration's (FDA's) practice to give individuals and firms an opportunity to take voluntary and prompt corrective action* ***before it initiates an enforcement action****. Warning Letters are issued to achieve voluntary compliance and* ***to establish prior notice****. (Prior notice is discussed in Chapter 10 - Other Procedures.) The use of Warning Letters and prior notice are based on the expectation that most individuals and firms will voluntarily comply with the law."*

Para 10-2-3 on Prior Notice states that

> *"When it is consistent with the public protection responsibilities of the agency and if a violative situation does not present a danger to health or does not constitute intentional, gross or flagrant violations,* ***it is FDA's practice to afford individuals and firms an opportunity to voluntarily take appropriate and prompt corrective action prior to the initiation of enforcement action****. If voluntary correction is not achieved, documentation that adequate prior notice was provided strengthens the agency's position in enforcement actions by establishing that responsible individuals continued violating the law despite having been warned by the agency."*

22. I note that apart from the above, para 4-1-1 of the USFDA Manual relied on by the Noticee also states that Warning Letters are issued only for violations of regulatory significance. Significant violations are those violations that may lead to enforcement action if not promptly and adequately corrected. The said para also states that in certain situations like when there is a violation of current good manufacturing practices, the USFDA may also take other actions as an alternative to, *or concurrently with, the issuance of a Warning Letter.* I note that the Warning Letter against the Noticee was issued for the violation of CGMP and therefore, as per the USFDA Manual, the Noticee was liable to other actions concurrently with the issuance of Warning Letter. Therefore, I do not agree with the Noticee's submission that warning letters are issued by the USFDA only as a guidance for individuals and firms to correct their practices before any enforcement action is initiated.

23. The Noticee has argued that a mere issuance of warning letter does not lead to any disruption in supplies and existing revenues, and therefore, it would have

had been a wrong disclosure if the Noticee were to make quantitative impact disclosure since on the day of issuance of warning letter there was no such foreseeable impact. The USFDA's Warning Letter dated October 09, 2021 clearly states that until the Noticee corrected all the violations completely and USFDA confirms compliance with CGMPP, USFDA may withhold approval of any drug applications or supplements listing the Noticee as a drug manufacturer. The aforesaid letter also stated that failure to correct the violations may also result in FDA refusing admission of articles manufactured at the Jadcherla facility into the United States. I note that the issuance of Warning Letter is a precursor to the aforesaid actions if the violations stated in the said letter are not corrected. Therefore, the possible repercussions of non – compliance as mentioned in the Warning Letter dated October 09, 2020 constitutes as "material" and ought to be have been disclosed to the investors. Keeping the above in view, I find that the Noticee has violated Regulation 30 of the LODR Regulations.

24. The Noticee, in its reply has stated that as per the USFDA Manual, issuance of Warning Letter is prior to initiation of any enforcement action and hence cannot be construed as a regulatory action by the Agency. Hence, the Noticee believed that they were not in violation of Clause 8 of Para B of Part A of Schedule III of the LODR Regulations.

25. I note that as per the USFDA Manual, Warning Letters are issued only for violations of regulatory significance. Para 10-2-2 of the USFDA Manual stated as under:

> *Except in a few specifically defined areas, the Food and Drug Administration (FDA) has no legal obligation to warn firms or individuals that they, their practices, or their products are in violation of the law prior to taking formal enforcement action. However, a basic principle of FDA's enforcement policy is the belief that the majority of persons will voluntarily comply with the law when given information as to what is required, what violations appear to exist, and, in the case of violations of regulatory significance, that failure to comply may result in the initiation of enforcement action.*

26. I note that being regulated by the USFDA, the Noticee was aware that in case of violations of regulatory significance like violation of CGMP, failure to comply may result in the initiation of enforcement action. I note that the term "regulatory action(s) with impact" means an action initiated by a regulatory body which may affect the prospects of the listed entity. The USFDA's Warning Letter dated October 09, 2021 stated until the Noticee corrected all violations completely and USFDA confirms compliance with CGMPP, USFDA may withhold approval of any drug applications or supplements listing the Noticee as a drug manufacturer and that failure to correct the violations may also result in FDA refusing admission of articles manufactured at the Jadcherla facility into the United States. Therefore, I find that the Noticee by not disclosing a regulatory action with impact was in violation of Clause 8 of Para B of Part A of Schedule III of the LODR Regulations.

27. In view of the above, I find that the Noticee by not making adequate disclosures has violated Regulation 4 (1) (d) and Regulation 30 (1) of the LODR Regulations, 2015 read with clause 8 of para B of Part A of Schedule III of LODR Regulations, 2015 and Section 21 of the SCR Act, 1956 read with clause 2 (i) of the Listing Agreement.

Issue No. II: Does the violation, if any, attract monetary penalty under Section 23 of SCR Act, 1956?

&

Issue No. III: If so, what should be the monetary penalty that can be imposed taking into consideration the factors mentioned in Section 23J of SCR Act, 1956?

28. The provisions of Section 23E of the SCR Act, 1956 read as under:

> ***Penalty for failure to comply with provision of listing conditions or delisting conditions or grounds.***
>
> ***23E.*** *If a company or any person managing collective investment scheme or mutual fund or real estate investment trust or infrastructure investment trust or alternative investment fund, fails to comply with the listing conditions or delisting conditions or grounds or commits a breach*

thereof, it or he shall be liable to a penalty which shall not be less than five lakh rupees but which may extend to twenty-five crore rupees.

29. A reading of the above section would make it abundantly clear that a company failing to comply with listing conditions shall be liable to a penalty which shall not be less than five lakh rupees but which may extend to twenty-five crore rupees.

30. The Noticee in its reply has stated that at the time of making disclosure, it has looked at the industry practice and that its disclosure has been in-line with the practice generally followed by the industry at large. During the hearing before me on March 03, 2022, the Noticee has also submitted some of the disclosures by other pharma companies such as Glenmark Pharmaceuticals Ltd., Cipla Ltd., Cadila Healthcare Ltd., Aurobindo Pharma Ltd., Panacea Biotec Ltd., Torrent Pharmaceuticals Ltd. and Divi's Laboratories Ltd., in receipt of Warning Letters.

Name of the Company	**Date of Disclosure**	**Contents of the Disclosure**
Divi's Laboratories Ltd.	April 22, 2017	*"Divi's Laboratories responded to the US – FDA inspection observations with an appropriate remediation process to overcome the deficiencies observed. As part of our commitments, we have also provided periodic updates to the US – FDA.* *…* *Divi's Labs, along with external consultants and subject matter experts, are working to address the concerns of the US-FDA and is making all efforts to fully meet the compliance requirements. We will respond to this Warning Letter with a detailed plan within the stipulated time."*
Aurobindo Pharma Ltd.	June 21, 2019	*"We believe the existing business from this facility will not be impacted. We will be engaging with the regulator and are fully committed in resolving this issue at the earliest. The Company is also committed to maintaining the highest quality manufacturing standards at all if its facilities across the globe."*
Glenmark Pharmaceuticals Ltd.	October 05, 2019	*"…the USFDA has now issued a "Warning Letter" to the Baddi facility. The company is committed to work along with the USFDA to implement all the necessary corrective actions required to address the concerns raised in the matter and is in process*

		of preparing a detailed response to the USFDA within 15 working days. *We believe that the existing manufacturing and the sale of products from this facility will not be impacted. The Baddi facility is expected to contribute USD 30mn in total sales for this financial year which is approximately 7% of the total US sales. There are no major pending approvals from this facility in the next 12 months There will be no financial impact on the organisation on account of this development.* *Glenmark currently has eight manufacturing facilities approved by USFDA – five formulations facilities and three API facilities under Glenmark Life Sciences Limited. None of these facilities except Baddi has any outstanding issues with the USFDA at this point in time."*
Torrent Pharmaceuticals Ltd	October 09, 2019	*"We will be engaging with the agency and are fully committed in resolving this issue at the earliest. The Company is also committed to maintaining the highest standards of compliances and quality manufacturing across all its facilities.* *The Company does not believe that the warning letter will have an impact of disruption of supplies or the existing revenues from operations of this facility."*
Cadila Healthcare Ltd.	November 04, 2019	*"…the Company has received a Warning Letter issued by the US FDA relating to its Moraiya formulation facility.* *…* *The Company has taken multiple steps after the inspection to address the observations received from US FDA during the inspection…We are confident of responding to US FDA to address the observations within the statutory time permitted in the letter.* *…* *This Warning Letter does not affect the existing business of the company in the US and the existing product supplies from the Moraiya facility will continue."*
Cipla Ltd.	February 26, 2020	"…*the Company has received a Warning Letter from USFDA. The Company remains committed to maintain the highest standards of compliance and will work closely with the agency to comprehensively address all the observations."*
Panacea Biotec Ltd.	September 30, 2020	*"1. The Company has received on September 25, 2020 a Warning Letter dated September 24, 2020 issued by the USFDA relating to pharmaceutical formulation facility at Baddi, Himachal Pradeh, owned by the Company's unlisted wholly owned*

		subsidiary, Panacea Biotec Pharma Limited ("PBPL"). *2. … The Company/ PBPL will actively engage with the agency and take all necessary steps required to address USFDA concerns. The Company/PBPL is also in the process of providing a thorough and comprehensive response to the USFDA within the statutory time permitted in the letter.* *3. This warning letter does not materially affect the existing business of the Company/ PBPL in the US and the existing product supplies from the said pharmaceutical formulations facility will continue. Further, US revenues from the said facility is not significant as compared to total revenues of the Company and PBPL. The USFDA may, however, withhold approval of any drug applications or supplements till PBPL addresses all issues raised by the agency.* *…* *5. In view of the above, the Company believes that this has no material impact on the business of the Company/ PBPL and therefore, it was disclosed to the Stock Exchanges earlier."*
Lupin	June 13, 2021	*"The Company does not believe that the warning letter will have an impact on disruption of supplies or the existing revenues from operation of this facility.* *We are committed to addressing the concerns raised by the US FDA and will work with the FDA and the New Jersey District to resolve these issues at the earliest. We uphold quality and compliance issues with utmost importance and are committed to be compliance with the Good Manufacturing Practice standards across all our facilities."*

I note that without knowing the background of the Warning Letters, the context in which they were issued and without hearing the said companies, details of the disclosures made by the aforesaid companies, it would not be appropriate to comment on the adequacy of their disclosures.

31. However, I note that SEBI has issued a Warning Letter dated June 24, 2022 to Aurobindo Pharma Ltd. (hereinafter referred to as "APL") for disclosing very limited and restricted information to the stock exchanges about receiving a warning letter from the USFDA.

32. I note that the Warning Letter dated June 24, 2022 issued by SEBI notes that on January 14, 2022, APL disclosed that the company had received a warning letter from the USFDA. SEBI inter alia observed that the company did not disclose the details on the reason and the non-compliance/ aberration observed, for which warning was issued. SEBI also observed that mere disclosure of the receipt of the USFDA warning letter is insufficient and an impediment to assess the current status. Therefore, SEBI in the aforesaid Warning Letter dated June 24, 2022 warned and advised APL to ensure compliance with all applicable provisions of SEBI Regulations, and further informed that any such aberration in future would be viewed seriously and appropriate action would be initiated.

33. I have perused the Warning Letter dated January 14, 2022 issued by the USFDA to APL which summarizes significant deviations from CGMP for active pharmaceutical ingredients (API) and states that as the methods, facilities, or controls for manufacturing etc., do not conform to CGMP, APL's API are adulterated. The USFDA's warning letter also stated that the USFDA may withhold approval of new applications until the deviations are completely addressed and that failure to address any deviations may also result in the USFDA refusing admission of articles manufactured at APL's Telangana facility into the United States. I note that the Warning Letter issued to APL by the USFDA is on the similar lines of the Warning Letter issued to the Noticee which is the subject matter of this proceedings.

34. In view of the above, although the Noticee has violated Section 21 of the SCR Act, 1956 read with clause 2 (i) of the Listing Agreement and Regulation 4 (1) (d) and Regulation 30 (1) of the LODR Regulations, 2015 read with clause 8 of para B of Part A of Schedule III of LODR Regulations, 2015, keeping in view that in a similarly placed matter SEBI has issued Warning Letter, I am not inclined to levy penalty and it would be sufficient to advise the Noticee to be careful and ensure compliance with all applicable provisions of SEBI Act, 1992, SCR Act, 1956 and Regulations framed thereunder.

ORDER

35. In view of the above, after considering all the facts and circumstances of the case in terms of Section 23 I of the SCR Act, 1956 read with Rule 5 of SCR (Procedure for Holding Inquiry and Imposing Penalties by Adjudicating Officer) Rules, 2005, the proceedings against the Noticee, Shilpa Medicare Limited are disposed of without imposition of any monetary penalty and the Noticee is advised to be careful and ensure compliance with all applicable provisions of SEBI Act, 1992, SCR Act, 1956 and Regulations framed thereunder.

36. In terms of the provisions of Rule 6 of the Adjudication Rules, a copy of this order is sent to the Noticee and also to the Securities and Exchange Board of India.

Sd/-

DATE: June 30, 2022 **D. V. SEKHAR**

PLACE: MUMBAI **ADJUDICATING OFFICER &**

CHIEF GENERAL MANAGER