

September 3, 2024

BSE Limited

P J Towers, Dalal Street,
Mumbai-400001

Code: 532321

National Stock Exchange of India Limited

Exchange Plaza,
C/1, Block G,
Bandra-Kurla Complex, Bandra (East),
Mumbai-400051

Code: Zyduslife

Re.: Clarification w.r.t. intimation dated August 30, 2024, regarding receipt of warning letter from USFDA

Dear Sir / Madam,

This is with reference to email dated September 3, 2024, received from Listing Compliances Department (“LISCO”), National Stock Exchange of India Limited (“NSE”), regarding submission of additional details w.r.t. intimation dated August 30, 2024 regarding receipt of warning letter from USFDA.

In this regard, please find below point wise response:

Sr. No.	Particulars	Details
1.	Name of the authority	United States Food and Drug Administration (USFDA)
2.	Nature and details of the action(s) taken, initiated or order(s) passed	A Warning Letter from the USFDA identifies the concern(s), such as gaps in manufacturing practices or violations with respect to current good manufacturing practices (cGMP). Zydus has received this letter for the injectable manufacturing facility situated at Jarod, near Vadodara, Gujarat. The letter provides an opportunity to the company to address USFDA's concerns, and it requests a response within a certain timeframe. The concerns noted by USFDA are already under remediation by the manufacturing site. Necessary corrective and preventive measures are being taken.

Zydus Lifesciences Limited

Regd. Office : 'Zydus Corporate Park', Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad-382 481, Gujarat, India. | Phone : +91-79-71800000, +91-79-48040000
website : www.zyduslife.com | CIN : L24230GJ1995PLC025878



Sr. No.	Particulars	Details
3.	Date of receipt of direction or order, including any ad-interim or interim orders, or any other communication from the authority	August 30, 2024
4.	Details of the violation(s)/contravention(s) committed or alleged to be committed	The warning letter summarizes certain violations with respect to current good manufacturing practice regulations.
5.	Impact on financial, operation or other activities of the listed entity, quantifiable in monetary terms to the extent possible	The Warning Letter does not impact the existing products manufactured and being supplied from the said injectable manufacturing facility to the US market and it also does not affect operations of the business. We do not expect any material or meaningful impact of the same on our financials.

Please find the above response in order.

Thanking you,

Yours faithfully,

For, **ZYDUS LIFESCIENCES LIMITED**

DHAVAL N. SONI
COMPANY SECRETARY

Zydus Lifesciences Limited

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