

May 28, 2024

To  The Corporate Relations Department BSE Limited Phiroz Jeejeebhoy Towers, 25 <sup>th</sup> Floor, Dalal Street Mumbai – 400001  <b>Code: 540222</b>	To  The Listing Department National Stock Exchange of India Limited, Exchange Plaza, Bandra Kurla Complex, Bandra (East) Mumbai – 400 051  <b>Code: LAURUSLABS</b>
--	--

Dear Sirs/Madam,

**Sub: Clarification /Confirmation on news item appearing in “Media/Publication”**  
**Ref: Your Letter dated May 27, 2024**

With reference to the above letter, we would like to inform you that the USFDA inspection took place in one of the units of our subsidiary company, viz. Laurus Synthesis Private Limited (LSPL) situated at Plot No.74B, Jawaharlal Nehru Pharma City, Parawada, Anakapalli district, Visakhapatnam from 4<sup>th</sup> December 2023 to 12<sup>th</sup> December 2023 and post-inspection form 483 was issued to LSPL with five observations. The fact of inspection by USFDA and issue of 483 with five observations was already communicated to the stock exchanges on 12<sup>th</sup> December 2023 by Laurus Labs Limited.

It may be noted that this Unit was acquired by LSPL in May 2020 from Phalanx Labs Private Limited during the Covid period. Prior to LSPL acquisition of this Unit, an import alert from USFDA was already in place from 2016 onwards. Upon acquisition of this Unit by LSPL, validation of in-house intermediates was undertaken and based on this, the USFDA undertook an inspection in December 2023.

Subsequently, the Company has submitted its response to the observations against which the USFDA on May 16, 2024 has issued an untitled letter providing another opportunity to address the deviations. As per the published USFDA regulatory manual, an untitled letter means an **initial correspondence** with the industry that cites violations that do not meet the threshold of a warning letter.

Further, LSPL is not a material subsidiary of the Company. Also, this LSPL Unit is not generating any revenues from the USA market and **no API US DMFs have been filed from this Unit so far**. This unit is very small unit and contributes less than 1% of the parent company's consolidated revenues.

*Cont'd...*

**Laurus Labs Limited**  
**Corporate Office**  
2<sup>nd</sup> Floor, Serene Chambers, Road No. 7  
Banjara Hills, Hyderabad - 500034, Telangana, India  
**T** +91 40 6659 4333, 3980 4333, 2342 0500 / 501  
**F** +91 40 6659 4320 / 3980 4320



To summarise, the receipt of the USFDA untitled letter was not communicated to the Stock Exchanges because of the following reasons:

- a. LSPL is not a material subsidiary of the parent company Laurus Labs Limited
- b. This Unit contributes to less than 1% of the parent company's consolidated revenues
- c. No US DMFs filed from this unit so far
- d. Untitled letter is an initial correspondence to the industry by the USFDA for violations that do not meet the threshold of a warning letter.

Therefore, we believe that we have not violated any materiality disclosure regulations.

This is for your information and record.

Yours faithfully,  
**For Laurus Labs Limited**

**G. Venkateswar Reddy**  
**Company Secretary &**  
**Compliance Officer**