



GLAND PHARMA LIMITED

August 26, 2023

BSE Limited
Corporate Relationship Department
Phiroze Jeejeebhoy Towers
25th floor, Dalal Street
Mumbai - 400 001
Scrip Code: 543245

National Stock Exchange of India Limited
Listing Department
Exchange Plaza, 5th floor
Plot no. C-1, Block G, Bandra Kurla Complex
Bandra (East), Mumbai - 400 051
Symbol: GLAND (ISIN: INE068V01023)

Dear Sir/Madam,

Sub: US FDA Inspection at Pashamylaram Facility, Hyderabad

We hereby notify that the Office of Medical Device and Radiological Health Operations (OMDRHO), United States Food and Drug Administration (US FDA) conducted Pre-Market Inspection covering US FDA's Quality System/Current Good Manufacturing Practice regulations for Medical Devices (21 CFR Part 820) at the Company's Pashamylaram Facility at Hyderabad from 23rd August, 2023 to 26th August, 2023. The Company has received 2 (TWO) observations on Form 483 with respect to ANDA filed for the product to be manufactured in a PEN device at the said Facility. There is no data integrity observation.

The Company is committed to address the observations and will submit its response to US FDA within the stipulated time.

Request to take the above information on record.

Yours truly,

For Gland Pharma Limited

Sampath Kumar Pallerlamudi
Company Secretary and Compliance Officer