

REGISTERED OFFICE

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Dated: February 27, 2025

To,
National Stock Exchange of India Limited
BSE Limited
Symbol: NSE: GRANULES; BSE: 532482

Sub: Update on US FDA inspection at Gagillapur Facility
Ref: Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015

Dear Sir/Madam,

Further to our communications dated September 07, 2024, December 3, 2024, and December 4, 2024, regarding the US FDA inspection at our Gagillapur facility and its classification as "Official Action Indicated" (OAI), we wish to provide the following update:

On February 26, 2025, the US FDA issued a Warning Letter to Granules' Gagillapur facility based on its inspection conducted in August 2024. The FDA has not indicated any further escalation. We will respond within the stipulated timeframe and seek a meeting with the FDA to demonstrate ongoing progress towards compliance. We remain confident that this matter will be resolved satisfactorily within a reasonable timeframe.

Manufacturing and distribution of existing products from the Gagillapur facility continue unaffected. However, the Warning Letter may temporarily impact the FDA review of pending product submissions from this site until the issue is resolved.

Following the FDA audit and six Form 483 observations, Granules has implemented a proactive and comprehensive remediation plan to strengthen compliance and reinforce product quality and safety at the Gagillapur site. As part of this initiative, we voluntarily paused manufacturing and dispatches in September to conduct a thorough risk assessment, ensuring no product contamination or patient safety concerns. Operations resumed following this assurance.

Our remediation plan encompasses comprehensive corrective and preventive actions (CAPAs), oversight by three independent consulting firms, continuous product testing, and monthly updates to the FDA.

Since September 2024, these independent consulting firms—that are subject matter experts in quality, compliance, and regulatory practices—have been engaged to assess and validate the effectiveness of our remediation efforts. They continue to collaborate closely with Granules, both on-site and remotely, to drive sustainable improvements and ensure long-term compliance.





The Warning Letter highlights four key areas previously outlined in the FDA Form 483 observations. Granules has made significant progress addressing all of the FDA observations across these four areas, with most corrective actions completed and the remaining ones on track as scheduled.

Granules has been providing regular updates to the FDA on the progress and effectiveness of these remediation measures through regular monthly updates. A key focus of these efforts remains risk mitigation, ensuring that there is no adverse impact on the safety or quality of products manufactured and distributed from the Gagillapur facility.

Granules' growth trajectory remains robust and diversified, underscoring that our strategy is not solely dependent on new product approvals from the Gagillapur site. Key drivers include new launches from our GPI facility in the US, growth from large-volume products in the US and Europe, capacity addition and commercialization of the greenfield formulation facility at Genome Valley, value chain advancements in Europe, and our expanding oncology pipeline from Unit V. These initiatives ensure sustained performance as we work towards resolving the Warning Letter status and reinforcing our commitment to compliance.

This is for your information and dissemination to the members of the exchange.

Thanking You.

For GRANULES INDIA LIMITED

**CHAITANYA TUMMALA
(COMPANY SECRETARY &
COMPLIANCE OFFICER)**

