



REGISTERED OFFICE

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Dated December 04, 2024

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/Mam,

This is in continuation of the recent communication dated December 03, 2024, regarding the US FDA classification of our Gagillapur facility under "Official Action Initiated" (OAI), we provide the following updates.

This classification does not impact the ongoing manufacturing, distribution, or sale of existing products from the site. However, it may impact review of pending submissions from Gagillapur for approval of new products, until the OAI status is resolved.

Granules has undertaken a proactive, voluntary and comprehensive remediation plan to address the six form 483 observations raised by the USFDA. As part of this effort, we voluntarily paused manufacturing and dispatches in September to conduct a thorough risk assessment, ensuring no product contamination or patient safety concerns. Operations and dispatches have since resumed following this assurance. Our voluntary remediation plan includes robust corrective and preventive actions (CAPAs), oversight by an independent third party, continued product testing for risk assessment, and regular monthly progress updates to the USFDA. To date, over 80% of CAPAs have been completed, with the remainder on track for closure by March 2025. We are now seeking a meeting with the USFDA to present our progress and request a potential reinspection.

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 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 OAI 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)**