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FDA issues warning letter to Dr Reddy's

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Dr Reddy's Laboratories has received a warning letter issued by the US FDA dated November 05, 2015 relating to its API manufacturing facilities at Srikakulam, Andhra Pradesh and Miryalaguda, Telangana, as well as Oncology Formulation manufacturing facility at Duvvada, Visakhapatnam, Andhra Pradesh.

This action follows the earlier inspections of these sites by the agency in November 2014, January 2015 and February 2015 respectively.

Dr Reddy's CEO, Mr G V Prasad said, "We take quality and compliance matters seriously and stand by our commitment to fully comply with the cGMP quality standards across all of our facilities. We will respond with a comprehensive plan to address these observations within the stipulated time-frame of 15 days. We will continue to actively engage with the agency to resolve these issues and we have also embarked on an initiative to revamp our quality systems and processes, as an organization-wide priority."

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