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USFDA warns DRL on 3 plants

TIMES NEWS NETWORK

Mumbai/Hyderabad: The US Food and Drug Administration (USFDA) has issued a warning letter to Hyderabad-based Dr Reddy's Labs (DRL), raising concerns over quality compliance and manufacturing practices at its three plants. This follows the inspection of these sites by the agency in November 2014, and January and February 2015.

The company issued a statement on Friday that the US drug regulator had issued the warning, following inspections at its active pharmaceutical ingredients (API) manufacturing facilities in Andhra Pradesh and Telangana, as well as oncology formulation manufacturing plant at Visakhapatnam, Andhra Pradesh.

Reacting to the news, the company's stock tanked 15% to close at Rs 3,630 on Friday. The USFDA warning comes barely a week after the home-grown pharma giant clocked its highest ever quarterly sales in the second quarter of FY16.

Warning letters are issued for violations of regulatory significance, and may lead to enforcement action such as import alerts if the company does not take adequate action. This is the first instance when the company has faced regulatory scrutiny involving three facilities, after it had received an import alert on its Mexican chemical plant in July 2011.

"Dr Reddy's has received a warning letter issued by the USFDA, relating to its three plants Srikakulam, and Miryalaguda, Telangana, along with the oncology formulation business at Duvvada," the company's statement said, adding it will respond to the letter in 15 days.

Dr Reddy's said it will respond to the US drug regulator in 15 days

Commenting on the development, DRL CEO GV Prasad said, "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."

The company's Srikakulam facilities contribute around 10-12% of sales of the company. Analysts say the near-term performance of the company will be impacted. "According to the company's SEC filing, it had set up a new manufacturing facility in a Special Economic Zone in Duvvada, Visakhapatnam, for manufacturing of parenteral (injectable form) products. So the contribution of the Srikakulam plant should not be significant," an analyst said. Further, the impact of the API facilities would depend on how quick the company fixes the USFDA issues, or uses third-party sources.

Regulatory