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WARNING LETTER

USFDA flags 'serious violations' at Dr Reddy's

Will respond with plan ... within stipulated time, says firm

ENS ECONOMIC BUREAU
HYDERABAD, NOVEMBER 25

THE US Food and Drug Administration (USFDA) has warned Dr Reddy's Laboratories over serious data integrity violations, placing all its new applications or supplements under a cloud.

Making its letter public, USFDA has strongly worded that there are significant deviations from current good manufacturing practices (CGMP) for the manufacture of active pharmaceutical ingredients (APIs) for finished pharmaceuticals. This is likely to impact the company for new approvals by USFDA and may lead to drug import ban.

"Until you complete all corrections and FDA confirms your compliance with CGMP, FDA may withhold approval of any new applications or supplements listing your firm as a drug product or API manufacturer," the FDA letter said. It also noted that if the company fails to correct these violations, under Section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3), FDA may also refuse admission of articles into the US manufactured at CTO Unit VI, Srikakulam, AP, CTO Unit V, Miryalguda in Telangana and Unit VII, Duvvada, VSEZ, Visakhapatnam, Andhra Pradesh.

The USFDA was not satisfied despite Dr Reddy's sending responses nine times from December 15, 2014, to September 15, 2015. In a letter addressed to Satish Reddy, chairman, DRL on November 5, 2015, the regulator said several violations are recurrent or represent long-standing failures to adequately resolve significant manufacturing quality problems.

After receiving the warning letter, Dr Reddy's had said it will respond with a plan to address the observation within the stipulated time. "We take quality and compliance matters seriously and stand by our commitment to fully comply with the cGMP quality standards across all our facilities," GV Prasad, chief executive, Dr Reddy's had said earlier.

There were serious data integrity violations, including the backdating of records and failing to provide pertinent data to regulators. This was included in the warning letters for three manufacturing facilities for Dr Reddy's, according the USFDA. The warning letter for Dr Reddy's Laboratories — for three sites in Telangana and Andhra Pradesh, India — notes several violations that are recurrent or represent "long-standing failures to adequately resolve significant manufacturing quality problems." FE

'LONG-STANDING FAILURES'

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Regulatory