PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

MINT, Delhi
Fri, 17 Feb 2017, Page 7
Width: 11.55 cms, Height: 16.48 cms, a4, Ref: 47.2017-02-17.37

Cadila's Gujarat plant gets US FDA clearance

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MUMBAI

Shares of drugmaker Cadila Healthcare Ltd shot up nearly 20% on Thursday after the company said the US Food and Drug Administration (FDA) had cleared its Gujarat plant after an inspection.

The US drug regulator had earlier issued a warning letter to the formulations facility at Moraiya in Gujarat for breach of good manufacturing practices.

"The US FDA inspected our Moraiya facility from 6 February, 2017 to 15 February, 2017. At the end of the inspection, no observation (Form 483) was issued," Cadila said in a stock exchange filing on Thursday.

The US FDA issues a Form 483 if its investigators spot any conditions that in their judgment may constitute violations of specific US laws.

Cadila shares soared 19.9% to close at Rs429.45 on the BSE, while the benchmark Sensex index rose 0.5% to close at 28,301.27 points on Thursday.

"Resolution of compliance issues at Moraiya was very critical as this plant accounted for 60-70% of the company's sales in the US. This is a big positive. Cadila will start getting approvals for products that were stuck due to regulatory issues at Moraiya," said an analyst, who did not wish to be named. The plant was issued a warning letter in December 2015, nearly a year and a half after the US regulator had issued a Form 483.