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Lupin gets warning letter from USFDA for Goa, Indore units

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The company had earlier received three form 483 observations for the Goa facility on April 7, 2017 and six form 483 observations for Pithampur (Unit II) on May 19, 2017

Pharma company Lupin has announced that it has received warning letter from the US health regulator for its manufacturing facilities in Goa and Indore.

According to the company statement, "The company has received a warning letter issued by the United States Food and Drug Administration (USFDA) on November 6, 2017 for our formulation manufacturing facilities at Goa and Indore (Pithampur Unit II). The company had earlier received three form 483 observations for the Goa facility on April 7, 2017 and six form 483 observations for Pithampur (Unit II) on May 19, 2017, and responded to all the observations."

The company is deeply disappointed to have received this outcome, adding that while there will be no disruption of product supplies from either of these locations, there is likely be a delay of new product approvals. We plan to address the concerns raised by the USFDA expeditiously and will work with the USFDA to resolve these issues at the earliest."

The company upholds quality and compliance issues with utmost seriousness and remains fully committed to be compliant with cGMP quality standards across all the facilities, it added.