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Sun response to import ban inadequate, says FDA

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Reuters

BANGALORE/ MUMBAI: Generic drugmaker Sun Pharmaceutical Industries's response to an import ban on one of its plants lacked sufficient corrective actions, the US food and drug administration said in a warning letter published on Tuesday.

The FDA banned imports from Sun Pharma's Karkhadi plant in Gujarat in March, but the reason for the ban was not clear at that time.

In the warning letter dated May 7 and posted on the FDA website on Tuesday, the regulator said Sun Pharma failed to ensure laboratory records had complete data and that manufacturing staff had inadequate training and experience.

Your firm frequently performs 'unofficial testing' of samples, disregards the results, and reports results from additional tests, the FDA said in the letter addressed to Sun Pharma CEO Subramanian Kalyanasundaram.

A Sun Pharma spokesman told Reuters on Tuesday that the warning letter shows that the US FDA does not agree with the company's response.

The Karkhadi plant, which makes the antibiotic cephalosporin, is one of Sun Pharma's 25 manufacturing plants.

Sun Pharma, which is planning to buy its struggling rival Ranbaxy Laboratories for $3.2 billion, had said in March that the import ban would have negligible financial impact.

The FDA has unleashed a wave of restrictions, warnings and bans on Indian generic drug firms over the past one year, citing serious manufacturing and quality control problems.

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