

FDA to expand Sun Pharma data scrutiny

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Sun Pharmaceutical Industries Ltd seems headed for more trouble with the US Food Drug Administration (FDA), which in its latest letter to the company on its Karkhadi factory in Gujarat has pointed to company-wide data integrity issues similar to those that plagued Ranbaxy Laboratories.

In April, Sun acquired Ranbaxy in a deal worth \$3.2 billion.

The 7 May letter, posted on the FDA's website, which says Sun's response to FDA's earlier findings is inadequate, was reported in Indian media, including *Mint*, on Wednesday.

What the reports missed out was that the US regulator was raising concerns about the integrity of "all data" generated by Sun Pharma.

FDA, which has banned imports from Sun Pharma's factory in Karkhadi, is expanding its scrutiny to the company's other factories, including the two export-oriented ingredient production sites and two formulation units located in Gujarat, Maharashtra and Dadra

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