

Data integrity issue already mentioned in USFDA warning letter: Sun Pharma

BS REPORTER

New Delhi, 4 December

Generic drugmaker Sun Pharmaceuticals, in the process of acquiring Ranbaxy, issued a statement on Thursday, clarifying that the issue about data integrity in its Karkhadi plant, Gujarat, was already mentioned in the US Food and Drug Administration (FDA) warning letter of May 2014.

"Since then, till now, there is no additional data or new observations on Karkhadi." Sun was reacting to a report by *Bloomberg*, carried in this newspaper, on the company deleting some of its quality-linked data ahead of USFDA inspection of the plant in 2011, raising the question of data integrity.

"Hence we are not sure why this issue is being raised at this point in time. On the specific question of data integrity at Karkhadi, it is important for us to highlight that the USFDA observations were taken seriously and necessary changes to the relevant systems and equipment have

been made," spokesperson of Sun Pharma stated.

The spokesperson further added that the company is continuing to work hard on remediating balance issues at Karkhadi to ensure that the unit returns to compliance.

"In fact some of these changes are also being rolled out to other factories within the Group as part of our commitment to compliance."

On Halol, another Sun Pharma plant in Gujarat, there have been no such data integrity observations, the company said. "We have an internal team assisted by external experts working on resolving the 483 observations made by USFDA. We stay fully committed to comply with all regulatory requirements."

Despite acceptance of there being some compliance gaps, as well as our sincere intent and significant efforts currently underway to remediate our units, it is unfortunate that past events are being revived and misrepresented, the spokesperson pointed out.

Pakshi