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Cipla Gets FDA Observations for Indore Unit

Our Bureau

Mumbai: The US Food and Drug Administration has identified nine areas of concern that need correction at Indian drug maker Cipla's manufacturing unit at Indore.

Cipla is among the few large domestic companies that has so far not faced any tough regulatory action from the FDA.

As part of its observations made during an inspection of the plant in July and August, FDA investigators Ademola Daramola and Nebil Oumer noted that the quality control unit lacked the authority to review production records to ensure that no errors have occurred and to investigate any mistakes made.

They said that although one batch of levalbuterol inhalation solution was recalled from the US in May 2015, "the investigation did not extend into other strengths of the product to determine the product's quality, safety and stability."

In another observation, they said a failure related to a leakage was documented 35 times but no study was initiated to identify problems that could potentially affect product safety and quality.

The FDA officials faulted Cipla's Indore unit for facility and equipment systems and noted that the aseptic processing areas were deficient in monitoring environmental conditions.

In an observation related to quality parameters, the FDA staff noted that the sterile filling lines were frequently opened in order to complete manual interventions. "In the packaging hall, sterile product vials exiting the filling line were handled with ungloved and unsanitised hands by packaging line employees," the inspectors said.

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