
Sun Pharma's Karkhadi unit gets USFDA warning

NEW DELHI: The US health regulator has warned Sun Pharma it may withhold approval of new drug applications and extend an import ban at its Karkhadi unit in Gujarat if violations of manufacturing norms at the facility are not corrected. The US Food and Drug Administration said there were reasons to suggest a general lack of reliability and accuracy of data, including missing fundamental raw data, unacceptable data handling practice and inadequate investigation into "the pervasive practice of deleting (raw) files".

Regulatory