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Many FDA-approved plants in India

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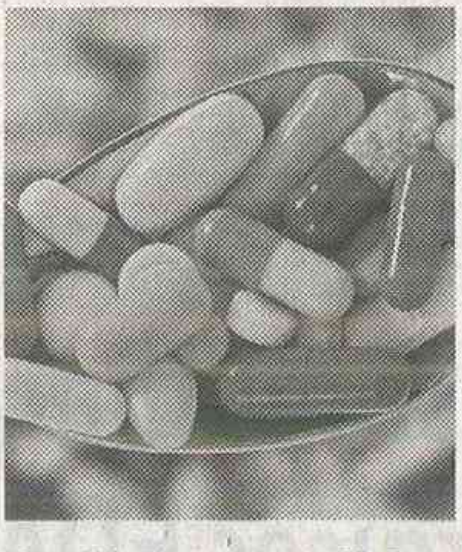
India supplies 40 per cent of the generic medications consumed in the US, where copycats account for more than 8 in 10 prescriptions.

"On the Indian side, they are mindful from a reputation standpoint this is not doing any good," said Sujay Shetty, head of the Indian pharmaceutical and life-sciences practice at consultancy PwC. "From a supply point of view–for your customers, for the functioning of your business– there's a lot of disruption you have to deal with."

Footage from closed-circuit cameras showed documents resembling manufacturing and packaging records were being shredded at the Jadcherla factory of Hetero Labs in India's Telangana state, FDA said.

The closely held company told inspectors that the tapes showed workers cleaning, though officials weren't able to explain why the



shredder was installed or why the work began 4 days before FDA inspectors arrived, the regulator said in its report, called a Form 483. A firm is generally given time to respond to the observations in a Form 483 before the regulator determines if actions need to be taken.

"When FDA finds that manufacturers lack sufficient controls over the integrity of their data, or worse, when firms intentionally violate such controls, those manufacturers' practices raise questions about the accuracy, reliability, and truthfulness of all the data and information they collect and report," said Lyndsay Meyer, a spokeswoman for FDA, in an e-mailed response to a question about the shredding activity noted at Hetero Labs. "While some Indian firms meet US product quality standards, others do encounter problems and operational challenges."

The Indian pharmaceutical industry's explosive growth over the past decade has made the nation host to the most FDA-approved plants outside the US. The regulator has increased staff in India in recent years, facilitating an inspection blitz that uncovered violations at multiple firms – ranging from deleted data to unsanitary conditions – and resulted in regulatory sanctions, including import bans.

Since then, months of costly remediation efforts have some company executives signalling they are ready to invite inspectors back to see whether sanctions can be lifted.