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After FDA concerns, Ipca halts drug shipment to US

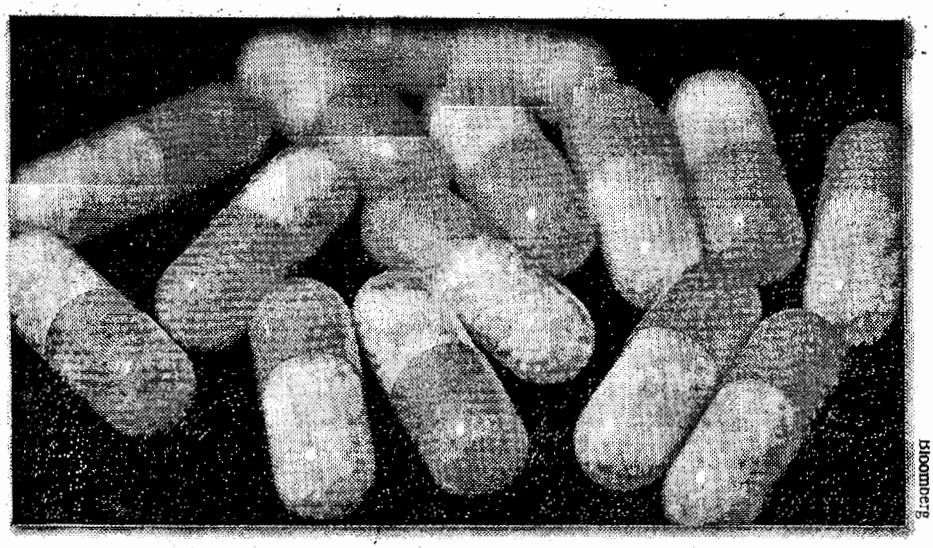
Firm will have to respond to the observation within a fortnight

TRUSHNA UDGIRKAR
Hyderabad

AFTER a regulatory whip from the USFDA, IPCA Laboratories has voluntarily halted shipments of drug ingredients made at their manufacturing plant at Ratlam in Madhya Pradesh. The FDA in their inspection held earlier this month issued the Indian company, Form 483 which details the violations at the plant.

The move would also impact their formulations export business to the US markets as the formulations manufacturing units situated at Piparia (Silvassa) and SEZ, Indore (Pithampur) use the APIs manufactured from the company's Ratlam manufacturing facility for manufacturing formulations for the US market, IPCA said in a statement.

The company will now have to respond to the observation within half a month with a detailed plan and timeline to resolve the issues.



Bloomberg

TOUGH TIME: For IPCA, the US market contributes sales of Rs 419 crore to 12 per cent of total sales and 20 per cent of total exports

The observations made in the Form 483 are of violations of the Food Drug and Cosmetics Act and other wrongdoings be it related to equipment, staff or practices.

For IPCA, US market contributes sales of Rs 419 crore – which amounts to 12 per cent of total sales and 20 per cent of exports.

"The net impact on the company would depend on the time it takes to come out of the same or shift its business to other USFDA approved facility. Thus, we expect the FY 2015 sales to be impacted, while FY 2016 should remain same. As of now, we have reduced our sales and net profit by 4 per cent for FY15," said Sarabjit Kour Nangra, vice-president research — Pharma, Angel Broking.

trushnaudgirkar
@mydigitalfc.com

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