

USFDA warning to Canton Labs over test forgery

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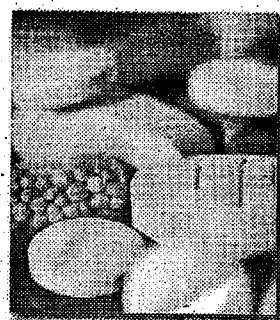
Bloomberg

WASHINGTON: An Indian company that says it supplies ingredients for major drug makers was warned by US regulators for forging test results and failing to properly clean equipment.

The Food and Drug Administration (FDA) is stepping up enforcement in India where growing quality concerns have led the agency to ban US sales from some factories. Canton Laboratories of Vadodara was warned in a letter dated 27 February for a variety of manufacturing practices, including reporting results for tests it never performed to measure microorganisms in active ingredients and failing to ensure equipment was cleaned to prevent contamination.

As a result of the agency's crackdown, factories run by Ranbaxy Laboratories and Wockhardt, both based in India, have been banned from supplying drugs to the US after being warned for manipulating test results and poor sanitation.

FDA Commissioner Margaret Hamburg visited India



On alert

■ Canton Laboratories was warned in a letter dated 27 February for manufacturing practices

■ Ranbaxy and Wockhardt have been banned from supplying drugs to the US

to discuss quality issues last month.

Ranbaxy and Sun Pharmaceutical Industries, also based in India, are separately recalling cholesterol-lowering and diabetes pills after complaints of bottling mix-ups listed in an FDA enforcement report on 5 March.

The FDA's letter posted online on Wednesday stemmed from a nine-day inspection of Canton in April 2013.

Regulatory company