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Ranbaxy taking 'stringent steps' to end US FDA ban

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India's biggest drugmaker by sales, Ranbaxy Laboratories, has assured shareholders it is taking "stringent steps" to resolve a US ban on imports of medicines made at its newly renovated showcase plant.

The US Food and Drug Administration (FDA) banned imports last week from Ranbaxy's "ultra modern" Mohali plant, whose renovation was supposed to mark a turning point for the generics giant after years of run-ins with US regulators.

But now Mohali—along with two other Ranbaxy plants placed under FDA bans earlier—are unable to ship to the company's key US market due to for failing to meet "good manufacturing practices".

"Ranbaxy would like to assure all stakeholders we are taking stringent steps to address all (the FDA's) concerns," Ranbaxy chief executive Arun Sawhney told shareholders in a letter posted late Saturday on the company's website.

Ranbaxy is more than 60 percent owned by Japan's Daiichi Sankyo, which bought the firm in 2008 believing its dominance in cheaper generic medicines and developing markets would help the Japanese firm grow sales as Daiichi's drugs came off patent.

It outbid rivals to buy Ranbaxy for $4.6 billion. But its foray into the high-growth copycat drugs arena has brought the Japanese drugmaker only financial pain as the Indian firm has come under fire over a string

of safety problems.

New Delhi-based Ranbaxy's shares were trading Friday at 334 rupees—less than half the 737 rupees Daiichi paid in 2008.

The latest FDA ban came just four months after Ranbaxy pleaded guilty to US felony charges of selling adulterated antibiotic, epilepsy and other drugs from the Dewas and Paonta Sahib plants—which are still unable to supply the US market—and paid a record $500 million fine.

The fraud involving the two Indian plants was exposed by an ex-employee who said the 52-year-old company had created "a complicated trail of falsified records and dangerous manufacturing practices".

Announcement of the ban on Mohali's US exports wiped nearly $1 billion off Ranbaxy's share value earlier in the week as a slew of brokerages downgraded the company's earnings prospects.

"We appreciate more is expected from Ranbaxy and will continue to work together with the FDA for an early resolution of their concerns", not only with Mohali but with the other two plants, Sawhney said.

The Mohali plant was gearing up to produce off-patent copies of two blockbuster drugs—Novartis AG's blood-pressure pill Diovan and AstraZeneca Plc's stomach ulcer medicine Nexium.

"The Mohali plant is crucial for (Ranbaxy's) future growth" and the ban "could be a huge setback for the company," said Sarabjit Kour Nangra, a vice-president of Mumbai's Angel Broking.

FDA inspectors found tablets with a "black fibre" suspected to be human hair and pills with apparent machinery oil "black spots" at the Mohali plant. Last year, glass was detected in some pills made at the plant.

A spokesman for Ranbaxy declined Saturday to comment on media reports that the FDA now was scrutinising Ranbaxy's US-based Ohm Laboratories for potentially breaching the US Food, Drug and Cosmetic Act.

Ohm Laboratories is Ranbaxy's only facility making medicines for the US market, even though the company has a total of eight plant sites in India.

The US has traditionally accounted for some 40 percent of Ranbaxy's revenues.