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India's Ranbaxy promises to address issues over US ban

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India's Ranbaxy Laboratories, one of world's biggest generic drug makers, said Tuesday it would take "all necessary steps" to help lift an import ban by the US health regulator on one of its factories.

The US Food and Drugs Administration (FDA) issued an alert on Friday against the factory at Mohali in the northern state of Punjab, spelling more bad news for the company that has been marred by nearly 10 years of US-led regulatory action.

The latest ban saw Ranbaxy shares tumble as much as 35 percent at one point on Monday and several brokerages downgraded their investment rating on the stock, citing concerns over the future of the plant. The US is the world's biggest drugs market and accounts for about 40 per cent of Ranbaxy's revenues.

Shares were up 3.37 percent in early trade on Tuesday.

"Ranbaxy will review the details and will continue to fully cooperate with the US FDA and take all necessary steps to resolve the concerns at the earliest," the group said in a statement.

It expressed hope of an "early resolution" to the concerns.

Mohali is the third Ranbaxy factory to face US scrutiny. The Paonta Sahib facility in northern India and the Dewas plant in the country's centre were both earlier blacklisted from producing drugs for the US

market on manufacturing concerns.

According to an FDA "consent decree", Mohali—like the other plants—cannot supply drugs for the US until the regulator reinspects the facilities and is satisfied that all corrective measures have been taken.

Ranbaxy will also have to hire an independent consultant to inspect the factory and certify to the FDA that its processes and controls are in order and complying with good manufacturing norms.

In May Ranbaxy pleaded guilty to US charges of selling adulterated antibiotic, acne, epilepsy and other drugs and agreed to a record $500 million fine. The episode was a huge blow to its image.

The company also admitted making false and fraudulent statements to the FDA in 2006-2007 about stability tests on several other export drugs.

The US fraud, uncovered over eight years, was exposed by a whistle-blowing ex-employee who said Ranbaxy created "a complicated trail of falsified records and dangerous manufacturing practices".