Indian drugmaker Ranbaxy faces new US regulation woes (Update 2)

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Shares in Indian generic drugs giant Ranbaxy Laboratories crashed by as much as 35 percent on Monday after the US Food and Drug Administration suspended imports from one of its factories.

The FDA issued an alert on Friday against the factory at Mohali in the northern state of Punjab, spelling more bad news for Ranbaxy which is struggling to live down a nearly decade-long history of US-led regulatory action.

Ranbaxy, one of the world's biggest generic drugs makers, slid 34.99 percent to a day's low of 297.25 rupees on the Bombay Stock Exchange in early trading.

By the end of the day, some brokerage firms had downgraded the stock, citing concerns over the future of the Mohali plant. Shares closed down 30.27 percent at 318.85 rupees.

A spokesman for Ranbaxy, which was bought by Japan's Daiichi Sankyo group in 2008, said "the company has so far not received any communication from the US FDA" and it was seeking information.

The FDA website did not explain the reasons for the "import alert".

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 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".

Ranbaxy imported adulterated batches of drugs made in its Paonta Sahib facility near the Indian city of Chandigarh, which FDA inspectors said had poor record-keeping and inadequate testing for the stability of the drugs over time.

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

The Paonta Sahib facility and another at Dewas in central India were blacklisted from producing drugs for the US market.

Ranbaxy is not alone in facing scrutiny from global regulators because of problems at its factories.

In July Britain's healthcare regulator recalled 16 drugs from Indian pharmaceutical firm Wockhardt after finding deficiencies at one of its plants in western India.

"The import alert could be a huge setback for Ranbaxy Labs," said Sarabjit Nangra, pharma analyst with Mumbai's Angel Broking, adding that import alerts can take months to resolve.

Ranbaxy will for now have to rely on its New Jersey-based Ohm Labs to service all its US business, Nangra said.

Sriram Rathi of Anand Rathi Research, which downgraded the Ranbaxy stock from a "buy" to "sell" rating after the alert, said there could also be delays in new product launches.

The US is the world's biggest drugs market and accounts for about 40 per cent of Ranbaxy's revenues.

India's government has been forced to defend the country's lucrative generic drug industry, which accounts for nearly $15 billion in annual exports.

The country has built a reputation as the "pharmacy to the world" for its production of life-saving generic

versions of medicines for poor nations that cost a fraction of those with brand names.