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USFDA banned Sun Pharma plant after finding rat traps

■ US inspectors found a laboratory at the drug maker's facility in India 'uncleanable'

Mumbai, April 25

US regulators who visited a Sun Pharmaceutical Industries drug plant in India before the facility was banned last month from exporting to the US saw testing flaws, a garbage pile-up, and a laboratory they called "uncleanable".

The Food and Drug Administration inspectors observed that some workers misrepresented test data and deleted undesirable results, according to an inspection report known as Form 483 that Bloomberg obtained via a Freedom of Information Act request. There were rodent traps and a strong smell of urine in a quality-control lab area and bathrooms were in "total disrepair", with what appeared to be human waste on a wall, the report said.

On March 12, the agency barred the antibiotics plant in Karkhadi, Gujarat, from exporting to the US, the factory's primary market. The findings of the November inspection haven't previously been reported, and the FDA didn't disclose specific reasons when announcing the ban.

"We have sent our response to the FDA and given that the facility now has an import alert, it's clear that the FDA does not agree with our view," Sun, India's largest drugmaker by market value, said in an emailed response to questions from Bloomberg News. "In this process, we have learnt and have resolved to work on further strengthening our systems and controls."

Sun this month agreed to buy Ranbaxy Laboratories, which has four factories banned by the FDA. Last year, Ranbaxy agreed to pay $500 million to settle a whistleblower lawsuit and federal criminal charges that the company sold adulterated drugs while lying about it to the regulator.

Indian drugmakers have become major sellers to the US as demand for cheaper generics rises. The industry is also an essential provider of affordable medicines at home and in other parts of the developing world such as Africa.

Drug factories in India are coming under greater scrutiny after the FDA imposed restrictions on several suppliers of generic medicines to the US for failing to meet manufacturing standards. Sun hasn't faced FDA curbs in the past five years even as the regulator barred some factories from Indian rivals including Ranbaxy and Wockhardt over the last year.

Spokesmen at Ranbaxy and Wockhardt didn't immediately respond to calls and emails seeking comment for this article.

Founded by Indian billionaire Dilip Shanghvi in 1983 with five psychiatry products and a single manufacturing facility, Sun has grown into a company with net sales of ₹1.12 lakh crore ($1.8 billion) in the year ended March 2013, with production sites in other parts of India and several countries including the US, Bangladesh, Hungary and Israel.

While Sun's banned facility contributed less than 1% of revenue in 2013, the stock could be affected if "operational risks become repetitive," Balaji Prasad, an analyst at Barclays in Mumbai, wrote in a March 13 note to clients. The facility has a negligible contribution to Sun's revenue, the company said when the FDA issued the import ban.

According to the FDA's November report, the inspectors reviewed Sun's record keeping and the integrity of its data at the plant, which makes cephalosporin antibiotics as well as bulk ingredients for the medication.

The inspectors observed that "analysts regularly delete undesirable chromatographic results, and products are retested without initiating an investigation". Manufacturing waste, old equipment and other garbage was seen in the facility's "perimeter manufacturing areas" making them susceptible to pests, the report said.

Sun has implemented corrective measures on cleanliness at the plant, and where testing procedures weren't properly followed, it has taken the "necessary disciplinary action" and replaced equipment, according to the email to Bloomberg News. The drugmaker said some of the FDA's observations were related to the surrounding areas of the buildings, and it hasn't made a final decision on whether to shut the facility.

The FDA in an emailed statement to Bloomberg News declined to comment further.

In 2009, the FDA ordered manufacturing to be halted at Sun's Detroit-based unit after a string of recalls over manufacturing defects. Three years later, the FDA cleared the subsidiary to resume operations with two products, according to a company statement at the time. Sun Pharma didn't immediately respond to an email requesting an update on that unit.

The FDA last year banned about 20 plants in India from exporting drugs to the US and warned several others.

The latest ban on Ranbaxy occurred in January, when the FDA barred one of its plants from exporting to the US after finding workers there overwrote raw data collected on samples over five months until they got acceptable results.

"It's not like our quality expectations are that radically different from the US," said Ajit Mahadevan, Mumbai-based leader of the life sciences consulting group, referring to the Indian drug industry. "It's just that in its execution, there's a lot less intensity perhaps, and people get away with a lot more."

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