FDA Halts Drugs From Top Indian Drugmaker's Plant

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U.S. health regulators have placed a ban on imported drugs from a factory operated by India's largest pharmaceutical company, Ranbaxy Laboratories, due to manufacturing and quality control problems.

The import alert, issued Friday by the Food and Drug Administration, effectively stops imports of 11 drugs from Ranbaxy's Mohali factory in Punjab province. The agency said Monday its inspectors uncovered multiple violations at the factory last year, including failure to investigate manufacturing problems and failure to follow quality-control standards.

"We want American consumers to be confident that the drugs they are taking are of the highest quality, and the FDA will continue to work to prevent potentially unsafe products from entering the country," said Howard Sklamberg, director of the FDA's office of compliance, in a statement.

Ranbaxy Laboratories Ltd. stock price fell by 30.3 percent to 318.40 rupees ($5.10) by the close of trading on the Bombay Stock Exchange.

Ranbaxy had no immediate comment on Monday.

Under the latest FDA action, Ranbaxy is prohibited from manufacturing drugs for the U.S. market at the facility. The company will have to hire an outside expert to inspect and certify that the facility meets FDA standards before it can resume shipping to the U.S.

With revenues of $2.3 billion for the last fiscal year, Ranbaxy is the leading drugmaker in India's $26 billion generic pharmaceutical industry, but it has faced penalties from U.S. regulators for years.

In May, the company's American subsidiary agreed to pay $500 million in fines and penalties for selling adulterated drugs and lying to federal regulators, the largest financial penalty against a generic drug company for violations of the Federal Food, Drug and Cosmetic Act, which prohibits the sale of impure drugs.

In late 2012, another subsidiary, Ranbaxy Pharmaceuticals Inc., was forced to halt production of a generic version of the cholesterol drug Lipitor to investigate how tiny glass particles got into the ingredients used for dozens of batches that had to be recalled. It was Ranbaxy's second recall of the drug in three months.

Two years ago, the FDA struck a deal that required Ranbaxy Laboratories Ltd. to undergo extra oversight and review from a third-party and improve its drug making.

The new sanctions against the Mohali facility are an expansion of this earlier settlement with the agency.