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US halts drug imports from Ranbaxy plant in India

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U.S. health regulators said Thursday they are barring imported drugs from an overseas factory operated by Ranbaxy Laboratories, India's largest drugmaker, due to quality control violations.

The Food and Drug Administration ban effectively stops the company from shipping drugs and raw ingredients from its Toansa plant in the Punjab province. A Jan. 11 inspection by FDA staffers uncovered factory workers retesting drug ingredients that had failed quality testing, in an apparent effort to return positive results. Those practices and others found at the plant violate manufacturing standards for drugmakers that do business in the U.S.

"The FDA is committed to ensuring that the drugs American consumers receive—no matter where they are produced—meet quality standards and are safe and effective," said FDA compliance director Carol Bennett.

Ranbaxy did not immediately respond to requests for comment Thursday.

Ranbaxy will be required to hire an outside inspector to review the plant and certify that it is meeting U.S. quality standards before the ban can be lifted.

In September the FDA placed a similar hold on imports from Ranbaxy's Mohali facility. Both actions were taken under a 2012 legal settlement

with the FDA, which subjects Ranbaxy to extra scrutiny and inspections to improve its drug production.

With annual revenue of more than $2 billion, 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.