

# USFDA warns Apotex's Bangalore facility for fraudulent drug data

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Reuters

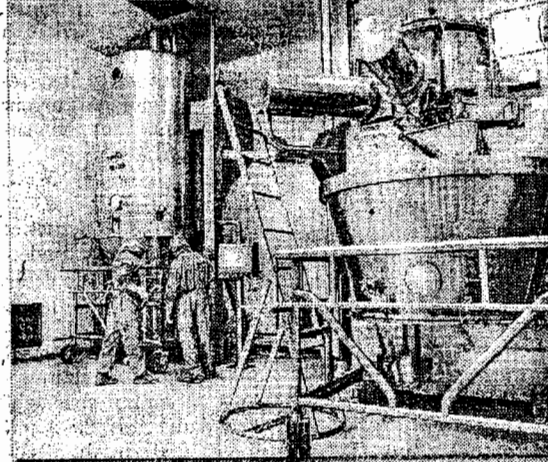
WASHINGTON: An Indian subsidiary of Canadian drug company Apotex manipulated laboratory data, retesting samples until the results were acceptable, according to a warning letter posted by the US food and drug administration on its website on Tuesday.

The letter, dated June 16, referenced an FDA inspection that took place in January at the company's facility in Bangalore, where inspectors found significant deviations from good manufacturing practices.

The inspection found that the company, which makes pharmaceutical ingredients, routinely completed sample analyses and recorded the data only if the results were acceptable.

If the results obtained were atypical, a fresh sample was to be prepared and analyzed, the FDA said in its letter. The original sample testing was not recorded.

In April, the FDA banned imports from the facility, saying it did not



**IN TROUBLE WATER:** In April, the FDA banned imports from the facility, saying it did not comply with quality standards

comply with quality standards. The move followed similar bans on certain products from Indian drug-makers Ranbaxy Laboratories, Wockhardt and Sun Pharmaceutical Industries.

The FDA said a response by privately held Apotex in February to the agency's inspection report lacks sufficient corrective actions and that the issues raised during the inspection demonstrate a general lack of reliability and accuracy of data

generated by your firm's laboratory.

The agency said the company's failure to create and maintain accurate documentation is a repeat observation reported to your facility during the 2006 and 2010 inspections.

The FDA said that until the company corrects all the deviations, it may withhold approval of any new product applications.

Apotex officials were not immediately available.

Apotex is a Canadian pharmaceutical corporation. Founded in 1974, the company is the largest producer of generic drugs in Canada, with sales exceeding \$1 billion (CAD) a year. The company produces more than 300 generic pharmaceuticals in approximately 4000 dosages, and 600 molecules under development. Apotex exports products to over 115 countries around the globe. There are more prescriptions filled with Apotex products in Canada than that of any other pharmaceutical company.

Apotex founded the Apotex Foundation, a privately held charitable organization, which has donated over \$17 million in medicines over the last 10 years. Critical medicines have been shipped to every disaster zone around the globe to provide assistance to humans in need. Apotex was also the only Canadian company to develop and manufacture a combination drug for AIDS patients in Rwanda.

Regulatory