

Another Indian pharma company rapped by FDA

22 October 2013 | News | By BioSpectrum Bureau



Singapore: After reports of Indian drug majors Ranbaxy Laboratories, Aurobindo Pharma, Dr Reddy's Laboratories and Wockhardt coming under the strict scrutiny of the US drug regulator, another Indian pharma firm is reportedly alleged of not adhering to the FDA's defined Current Good Manufacturing Practices (CGMP).

Smruthi Organics has come under the USFDA scanner for violation of norms at their production units both in India and overseas. The company has said that it has received a notification from the US FDA pointing out violations of manufacturing practices at its Solapur plant.

"US FDA has issued their observations in form 483. European Directorate for Quality of Medicines (EDQM) is yet to submit its final inspections report," Smruthi Organics said in a statement.

Form 483 is issued to a company after completion of an inspection when investigators observe conditions that may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts, notifying the objectionable conditions.

The statement said that both the US FDA and EDQM inspected its active pharmaceutical ingredients producing facility between October 14 and 18, 2013.