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RPG issued warning letter by US FDA

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Singapore: In what has come as another shocker for the Indian Pharmaceutical industry, the US FDA slammed RPG Life Sciences with a warning letter.

The US FDA is said to have found two manufacturing plants of the Indian pharma major, RPG Life Sciences, to be in violation of the current Good Manufacturing Practices (CGMP). The two plants under the US regulator's scanner are the ones at Ankleshwar and Mumbai. The US FDA has further warned the company that the failure on the part of their management to correct the violations may even result in a ban.

"During our November 20, 2012, through November 24, 2012, inspection of your pharmaceutical manufacturing facility, MS-Ankleshwar, investigators from the FDA identified significant violations of current good manufacturing practice (cGMP) regulations for finished pharmaceuticals," the health regulator said in a letter posted on its website.

Post investigations at the company's Navi Mumbai-based manufacturing facility, the FDA identified significant deviations from CGMP for the manufacture of active pharmaceutical ingredients (APIs).

"These violations cause your APIs and drug products to be adulterated. The methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, cGMP," US FDA further added.

USFDA further clarified that after conducting a detailed review of RPG Life Sciences' responses dated December 11, 2012 and February 19, 2013, they 'note that they lack sufficient corrective actions'.

"Until all corrections have been completed and FDA has confirmed corrections of the violations and your firm's compliance with CGMP, FDA may withhold approval of any new applications or supplements listing your firm as a drug product manufacturer," USFDA said.

The US regulator has warned that in case the company fails to correct the violations, it may result in banning of import of drugs manufactured at two of the company's facilities into the United States.