USFDA increases inspections of drug facilities in India

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NEW DELHI: The US Food and Drug Administration (USFDA) is increasing its inspections of facilities of drug makers in India, the second largest provider of finished dose products to the US, to ensure compliance of approved manufacturing norms.

The US health regulators, which has been cracking the whip against many Indian pharmaceutical firms, including Ranbaxy LaboratoriesBSE -1.07 % and WockhardtBSE 0.27 %, is also recruiting and training additional drugs investigators in India.

In order to meet requirements of the new Food and Drug Administration Safety and Innovation Act (FDASIA) - Generic Drug User Fee Amendments (GDUFA) , the USFDA said it is stepping up the inspections in India.

"In March 2013, the (US) FDA received approval from the Indian government to add seven additional drugs investigators in India. We are currently recruiting and training staff for these positions...," a spokesperson for USFDA Christopher C Kelly told PTI in an emailed response.

The USFDA's presence in India is being increased to 19 from 12 American staff based in-country, including 10 dedicated specifically to medical products. Other staff include foods and devices inspectors, and policy analysts.

"Having these additional inspectors in-country will assist the agency in meeting our legislative mandates. So we are increasing our rates of inspection," Kelly added.

Under the FDASIA, the USFDA is required to achieve the same inspectional schedule for foreign facilities as domestic manufacturers, and to clear the backlog of applications by the end of the first five-year user fee authorisation period.

Stressing on the importance for good compliance, Kelly said: "(US)FDA seeks to ensure that Indian manufacturing facilities importing to the United States understand the risks associated with their product's processes and assure they remain compliant to (US)FDA's regulations."

India, as the second largest provider of finished dose products to the US with almost 10 per cent of that market, has, for many years, been a consistent provider of low-cost and quality medical products for many countries of the world. he added.

"Our presence in India allows us to better collaborate with our Indian regulatory counterparts and enables us to leverage our combined resources, harmonise science-based standards and increase regulatory capacity."

In doing so, FDA continues to ensure that medical products moving in international commerce are safe, effective, and of high quality, he added.

"The (US)FDA remains confident that many companies understand and have implemented Good Manufacturing Practices (GMPs). We also remain vigilant and will take appropriate action if, or when, lapses, occur," Kelly said.