

USFDA bans Alkem Labs' arm from selling drugs in US

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The US arm of India's Alkem Laboratories has been banned from manufacturing and distribution of medicines in the US for selling unapproved drugs.

The US Food and Drug Administration (USFDA) said a federal judge from the US District Court entered a consent decree for permanent injunction against Ascend Laboratories, LLC — the US subsidiary of Alkem Laboratories — on October 10. The US Department of Justice filed the consent decree on behalf of the USFDA, it added.

"The consent decree requires Ascend Laboratories to post bond for the release of their unapproved drug products seized by US Marshals in May 2014, which the company is then responsible for destroying under the FDA's supervi-

What led to the ban

■ The USFDA inspected Ascend Laboratories' New Jersey facility in November 2013 and Masters Pharmaceutical's Cincinnati warehouse in February 2014. It found that Ascend Laboratories was marketing drug products without FDA approval and adequate directions for use.

sion," the statement said.

In addition, the consent decree prohibits Ascend Laboratories and all other associated persons who act in concert with the company from manufacturing and distributing unapproved drugs until the company obtains FDA approval, it added.

The USFDA inspected Ascend Laboratories' New Jersey facility in November 2013 and Masters Pharmaceutical's Cincinnati ware-

house in February 2014. "The inspections revealed that Ascend Laboratories was marketing drug products without FDA approval and adequate directions for use," the statement said.

"Manufacturing and distributing unapproved prescription drugs puts patients' health at risk since they have not been found to be safe, effective or made using quality manufacturing practices," FDA's Center for Drug Evaluation and Research acting director Ilisa Bernstein said.

"Companies that fall short of our requirements risk FDA action to stop the distribution of their products," Bernstein added. Alkem Laboratories is one of the top seven pharmaceutical companies in India. It has 15 manufacturing plants located across the country of which four are US FDA approved. — PTI

Regulatory