

India's Jubilant receives FDA warning for US plant

06 December 2013 | News | By BioSpectrum Bureau



Singapore: Jubilant Life Sciences has joined the list of leading Indian drug makers who have received a warning from the US Food and Drug Administration (FDA) over manufacturing and quality issues.

The company has said that it received a warning from the FDA over manufacturing practices at one of its facilities in the US facilities. As per the warning letter, FDA has said that it could even withhold approval of new products from the company's facility located in Spokane, Washington, until Jubilant HollisterStier takes action to comply with the regulator's good manufacturing practices.

The company said that it plans to respond to the warning on or before December 12 and will take corrective actions to ensure compliance with the FDA.

"We expect that the on-going manufacturing, distribution and sale of products from this facility will not be impacted as the warning letter will affect new approvals only," the company said in a statement.

The Washington facility accounted for 7 percent of Jubilant Life Science's consolidated sales in the six months ended September, reports pointed out.