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Jubilant resolves FDA warning for Montreal facility

SOUMONTY KANUNGO
Mumbai

JUBILANT Life Sciences, an integrated pharmaceuticals and life sciences company, on Friday announced a successful resolution to FDA warning letter for its Montreal facility.

The shares of the company jumped 6.86 per cent to Rs 124.55 on Bombay Stock Exchange post this announcement.

"Jubilant Life Sciences has received a communication from the US Food and Drug Administration (FDA), classifying its pharmaceutical manufacturing facility at Montreal, Canada, as "Acceptable". This resolves all issues raised by the FDA on the facility in February 2013 and subsequent communications," the company said in a statement.

The stock hit an intra-day high of Rs 126 and an intra-day low of Rs 121.50.

"The development follows completion of FDA's review of the company's responses post the February letter and the subsequent re-inspection conducted at Jubilant's Montreal facility in September, 2013. This development successfully resolves the FDA issues at our Montreal facility," the company added.

In February 2013, the company had informed BSE that one of its manufacturing facility, Jubilant HollisterStier General Partnership (JHS), located at Kirkland, Quebec, Canada was issued a warning letter by FDA identifying s ignificant violations of current Good Manufacturing Practices (cGMP) regulations.

"JHS' response will provide details as to what corrective action has already been completed, as well as, additional detail as to how the facility will prevent the reoccurrence of the items found to be objectionable to the FDA," the company had then said.

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- In 2013, the firm had informed BSE that a facility was issued a warning letter by FDA
- In December, the firm received another warning letter for one of its facilities at Washington
- It manufactures and supplies pharmaceutical ingredients, generics, specialty pharmaceuticals

In December, the company received another warning letter for one of its manufacturing facilities at Spokane, Washington.

According to a pharma analyst, this is a positive for the company as now the total impact on its overall revenue will come down to seven per cent from 14 per cent earlier since its Washington facility is yet to receive a positive communication from FDA.

The company, which manufactures and supplies active pharmaceutical ingredients (APIs), generics, specialty pharmaceuticals and life science ingredients, also provides contract manufacturing services and drug discovery and development.

(This report was published on our website on Friday night. We reprint here for the benefit of our print readers.)

soumonty.kanungo
@mydigitalfc.com

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