

Ranbaxy again under USFDA scanner, Stocks too take a dip

18 January 2014 | News | By Rahul Koul Koul

Ranbaxy again under USFDA scanner, Stocks too take a dip



At times when the company was trying its best to get back on track, the new year has brought a bad news for Ranbaxy. It received the form 483's with certain observations as a result of the recent US FDA inspection at its API plant at Toansa, Punjab, India. According to the Management, it's assessing the observations, and will respond to the US FDA in accordance with the agency's procedure to resolve the concerns at the earliest. While the Management has not indicated, the plant is said to manufacture around 70-75% of its API requirements.

Meanwhile the news had its effect on stock market too. The company's stocks dipped 4% to Rs 400 immediately after the news broke. However, now the company has gained a bit from there but is still down by 2.42% to Rs 406. The same will be now followed closely by the shareholders and industry alike.

An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. The FDA Form 483 notifies the company's management of objectionable conditions. At the conclusion of an inspection, the FDA Form 483 is presented and discussed with the company's senior management. Companies are encouraged to respond to the FDA Form 483 in writing with their corrective action plan and then implement that corrective action plan expeditiously, otherwise could lead to the import alert.

Ranbaxy Lab's other key facilities in India, i.e at Ponta Sahib (Himachal Pradesh) and Dewas (Madhya Pradesh), have been

under an US import alert since 2008. During the 2QCY2013, its other key facility Mohali also came under USFDA import alert. With this plant Toansa (Punjab) , also under scanner, it would have impact on the operations of the company in US, unless it can compensate for the same at the earliest and manage a smooth supply of key raw material.