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ASIA EDITION

Ranbaxy claims FDA form '483' not a show stopper

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Singapore: Soon after reports of Ranbaxy's Mohali manufacturing plant being issued a Form 483 by the US US FDA broke out, the company's stocks took a hammering in the market. However, the bigger threat was the potential loss that a regulatory ban at the company's newly commissioned and only US FDA approved plant in India would have on its business in the US.

Denying any US FDA inspection in 2013, the company spokesperson told *BioSpectrum Asia* that a Form '483' is not a show stopper. "There was no inspection of US FDA in 2013. A '483' is not a show stopper. We continue to make submissions from Mohali," Ranbaxy spokesperson said.

Ranbaxy's most popular cholesterol lowering drug, Atorvastatin, is currently reaching the US retail industry from the company's US-based subsidiary, Ohm Laboratories. However, the company is said to have moved key products from Ohm to the Mohali unit after experiencing capacity constraint at the former in 2011.

Battling questions regarding any regulatory action at the Mohali unit, the company spokesperson said, "Regarding atorvastatin, Ranbaxy can manufacture and supply the product from the Mohali plant to the US. We will begin supplies, once our market share and volumes become substantial."

In May, Ranbaxy pleaded guilty of felony charges in the US after accepting to have sold adulterated drugs in the US and concealed the facts from the investigators. The company has since then managed to retain its market foothold in the face of such reports. A Form 483, analysts claim is issued by the FDA when they find objectionable conditions that might be violation of laws, post inspection.