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Now Ranbaxy's Mohali unit under FDA scanner

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Singapore: Merely a month after Indian drug major, Ranbaxy, pleaded guilty of having misled the USFDA investigations, selling adulterated drugs in the US and paying a penalty of $500 million, the company is yet again said to have run into troubled waters.

News reports claim that after its Paonta Sahib plant, Ranbaxy's Dewas unit, which is the company's newly commissioned Mohali facility in India, appears to have come under the US FDA scanner.

Company insiders have revealed to the Indian press that after conducting an inspection of this plant at Mohali, the US FDA has issued a Form 483 to the company. The FDA issues a Form 483 to a company when they find objectionable conditions at the it's manufacturing unit that might be in violation of various laws. The company can, however, continue to make regulatory filing from that unit.

"We continue to make regulatory submissions from Mohali and will commercialize products from Mohali when we get approvals," a Ranbaxy spokesperson was quoted as saying in the Indian press.

Media reports further claim that FDA inspectors had visited the Mohali plant of Ranbaxy during the process of providing approvals for Ranbaxy's application for Valsartan, the generic version of Diovan by Novartis.