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ASIA EDITION

US FDA imposes import alert on Ranbaxy drugs

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Singapore: The US FDA has issued an alert on import of Ranbaxy Laboratories drug products that are manufactured at its plant in Mohali, India. The firm will remain on the import alert until the company complies with US drug manufacturing requirements of current good manufacturing practices (cGMP).

"The FDA is committed to using the full extent of its enforcement authority to ensure that drugs made for the US market meet federally mandated quality standards," said Mr Howard Sklamberg, director of the Office of Compliance in the FDA's Center for Drug Evaluation and Research. "We want American consumers to be confident that the drugs they are taking are of the highest quality, and the FDA will continue to work to prevent potentially unsafe products from entering the country."

The FDA also ordered that the Mohali facility be subject to certain terms of the consent decree of permanent injunction entered against Ranbaxy in January 2012. The decree contains provisions to ensure cGMP compliance at certain Ranbaxy facilities, including in Paonta Sahib and Dewas, India, as well as provisions addressing data integrity issues at those two facilities. Ranbaxy's Paonta Sahib and Dewas facilities have been on FDA import alert since 2008.

The FDA exercised its authority under a provision in the consent decree permitting it to order that terms of the decree be extended to a Ranbaxy-owned or operated facility if an inspection determines that the facility is in violation of Federal Food, Drug, and Cosmetic Act or FDA regulations, including cGMP. cGMP requirements serve as the primary regulatory safeguard over drug manufacturing and must be followed by companies to ensure manufacturing quality.

In September and December 2012, FDA inspections identified significant cGMP violations at Ranbaxy's Mohali facility, including failure to adequately investigate manufacturing problems and failure to establish adequate procedures to ensure manufacturing quality.

Under the decree, Ranbaxy is prohibited from manufacturing FDA-regulated drugs at the Mohali facility and introducing drugs into interstate commerce, including into the US, from the Mohali facility until the firm's methods, facilities, and controls used to manufacture drugs at the Mohali facility are established, operated, and administered in compliance with cGMP.

Ranbaxy is required to hire a third-party expert to conduct a thorough inspection of the Mohali facility and certify to the FDA

that the facilities, methods, processes, and controls are adequate to ensure continuous compliance with cGMP. Once the agency is satisfied that Ranbaxy has come into compliance with cGMP, Ranbaxy will be permitted to resume manufacturing and distribution of FDA-regulated drugs at the Mohali facility.