

FDA warns Tianjin Zhongan for cGMP lapses

26 June 2014 | Regulatory | By BioSpectrum Bureau



Singapore: The US Food and Drug Administration (FDA) has slapped a warning letter to China based Tianjin Zhongan Pharmaceutical company for manufacturing adulterated active pharmaceutical ingredients (APIs) caused by deviations of current good manufacturing practice (cGMP) at the plant.

The FDA has instructed Tianjin Zhongan Pharmaceuticals to take corrective measures of manufacturing compliance. The regulatory body has further warned the company that in the absence of compliance, the FDA may withhold approval of any new applications or supplements or ban admission of the company's drugs into United States.