

FDA issues warning letter to Cadila

01 January 2016 | News | By BioSpectrum Bureau

FDA issues warning letter to Cadila



Cadila Healthcare has received a warning letter from the United States Food and Drug Administration (US FDA) relating to its Moraiya formulation facility and Ahmedabad API facility (Zyfine).

Cadila said that it takes quality and compliance matters very seriously and stand by its commitment to fully comply with cGMP quality standards across all its facilities.

"The company is working hard to ensure that the commitments made to the US FDA are fully completed. The company will continue to take all necessary steps to ensure that the US FDA is fully satisfied with our remediation of the above facilities. Our products in the market are safe and effective and we are committed to supply the quality products to our customers across the globe," said Cadila in a statement.

"We hereby clarify that there are no products in the US market which use API of Zyfine facility. We will respond to the FDA to address the observations within the statutory time permitted in the letter. We are committed to resolve all the issues and revamp our quality systems and processes as the top most priority," said Cadila in a statement," the company added.