

Now, FDA issues warning letter to Sun Pharma

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Sun Pharmaceutical has announced that it has received a warning letter from the US Food and Drug Administration (US FDA) as a result of the September 2014 inspection, for its facility located at Halol, Gujarat in India.

Sun Pharma responded to the US FDA inspection observations with a robust remediation process that is still on-going, with significant investments in automation and training to enhance its Quality Systems. Sun Pharma has been working with external consultants to ensure its remediation activities have been completed in an appropriate manner.

Commenting on the development, Mr Dilip Shanghvi, managing director, Sun Pharma said, "While our team is working hard to ensure that the commitments made to the US FDA in September 2014 are fully completed, we will continue to cooperate with the US FDA and undertake any additional steps necessary to ensure that the US Agency is completely satisfied with our remediation of the Halol facility. Sun Pharma has always ensured that its products are safe and effective and there is no doubt on the safety of our products in the market. We are pledged to being cGMP compliant and are committed to continuing to supply our customers and patients across the world with quality products that meet all specifications."

Since the inspection in September 2014, Sun Pharma has communicated regularly with the US FDA on the progress of its remediation and on issues of product supply. It has provided periodic updates to the US FDA on its commitments. Post the September 2014 inspection, the US FDA has withheld future product approvals from the Halol facility. This situation may continue until all issues are resolved. Sun Pharma expects to request a re-inspection by US FDA upon completion of its remediation commitments.

Sun Pharma and the Halol facility will continue to supply important drug products to meet its obligations to its customers and the patients who use its drugs in the United States and around the world.

The company said it will respond to this warning letter with a detailed plan within the stipulated time frame.