

Sun Pharmaceutical Industries Ltd.
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CIN: L24230GJ1993PLC019050
www.sunpharma.com



FOR IMMEDIATE RELEASE

Sun Pharma receives Warning Letter for Halol facility

Mumbai, December 19, 2015: Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, Sun Pharma) today announced that it has received a Warning Letter from the 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, 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.

Sun Pharma will respond to this Warning Letter with a detailed plan within the stipulated time frame.

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Conference call (06.00 pm IST, December 19, 2015)

The Company will conduct an hour long call at 06.00 pm IST on December 19, 2015 where senior management will discuss and answer questions from participants. To participate in this conference call, please dial the numbers provided below, five to ten minutes ahead of the scheduled start time. The operator will provide instructions on asking questions before the call. You can also hear the call via an audio webcast, details of which will be announced later on the Company website, www.sunpharma.com. A transcript of this conference call will also be available on the website.

Summary of events

Event	Date and time	Telephone number/ website
Conference call	06.00 pm IST, December 19, 2015	Primary Number : +91 22 3960 0899 Secondary Number : +91 22 6746 8324 Via audio webcast, details of which will be made available on www.sunpharma.com
Replay of conference call	December 19, 2015 to December 27, 2015	India: +91 22 3065 2322 ID: 74861 Via audio webcast playback, details of which will be made available on www.sunpharma.com

About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050)

Sun Pharma is the world's fifth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business, economies of scale and an extremely skilled team enable us to deliver quality products in a timely manner at affordable prices. It provides high-quality, affordable medicines trusted by customers and patients in over 150 countries across the world. Sun Pharma's global presence is supported by 49 manufacturing facilities spread across 6 continents, R&D centres across the globe and a multi-cultural workforce comprising over 50 nationalities. The consolidated revenues for 12 months ending March 2015 are approximately US\$ 4.5 billion, of which US contributes US\$ 2.2 billion. In India, the company enjoys leadership across 13 different classes of doctors with 30 brands featuring amongst top 300 pharmaceutical brands in India. Its footprint across emerging markets covers over 100 markets and 6 markets in Western Europe. Its Global Consumer Healthcare business is ranked amongst Top 10 across 4 global markets. Its API business footprint is strengthened through 14 world class API manufacturing facilities across the globe. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities comprising about 2,000 scientists and R&D investments of over 7% of annual revenues. For further information please visit www.sunpharma.com & follow us on Twitter @SunPharma_Live.

Contacts

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