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Caraco receives USFDA clearance to resume operations

Mumbai, August 28, 2012: Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE:SUNPHARMA, BSE: 524715) announced that subsequent to inspections earlier this year and corrective action on 483's, USFDA has determined Caraco to be in compliance with relevant paragraphs of the Consent Decree. Therefore, USFDA has notified that Caraco may resume operations at its manufacturing facility and packaging sites in Detroit and Wixom, Michigan.

During their inspection, the USFDA reviewed the certification reports for production of Carvedilol USP as well as Paramomycin USP, and subsequently reviewed corrective actions on 483's. Currently, Caraco may resume products of only these two products.

Manufacturing of other products from these sites, including those pending approval with the USFDA, will be subject to similar rigorous approval procedure. As a result, the increase in production at these sites and resultant revenue contribution is expected to be gradual.

With reference to other requirements of the same Consent Decree, Caraco is required to now work with an external auditor conducting regular inspections for an extended period.

About Sun Pharmaceutical Industries Ltd.

Established in 1983, listed since 1994 and headquartered in India, Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715) is an international, integrated, speciality pharmaceutical company. It manufactures and markets a large basket of pharmaceutical formulations as branded generics as well as generics in India, US and several other markets across the world. In India, the company is a leader in niche therapy areas of psychiatry, neurology, cardiology, diabetology, gastroenterology, and orthopedics. The company has strong skills in product development, process chemistry, and manufacturing of complex API, as well as dosage forms. More information about the company can be found at www.sunpharma.com.

Contacts

Mira Desai
Tel +91 22 6645 5645, Xtn 606
Tel Direct +91 22 66455606
Mobile +91 98219 23797
E mail mira.desai@sunpharma.com