

Sun Pharma arm gets FDA clearance for facilities in the US

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Mumbai: Sun Pharmaceutical arm Caraco has received clearance from the US Food and Drug Administration (FDA) to resume operations at its facilities in Detroit and Wixom, Michigan.

The clearance came following inspections earlier this year. The US FDA has notified that Caraco may resume operations at its manufacturing facility and packaging sites in Detroit and Wixom, Michigan.

During their inspection, the US FDA reviewed the certification reports for production of Carvedilol USP as well as Paramomycin USP, and subsequently reviewed corrective actions on 483's. Currently, Caraco has been allowed to 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.