

USFDA lifts import alert from Dr. Reddy's facility at Mexico

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Mumbai: The US FDA's import alert at Quimicas Falcon de Mexico SA de C.V. (chemical manufacturing facility at Cuernavaca, Mexico), a wholly owned subsidiary of Dr. Reddy's Laboratories, has been lifted. Dr. Reddy's received a clearance from the US Food and Drug Administration (USFDA) on July 26, 2012.

Dr. Reddy's Mexico facility was inspected by the USFDA in November 2010. Based on observations by the USFDA, a warning letter was shared on June 14, 2011, with the company. Dr. Reddy's worked with USFDA to resolve the observations in the warning letter. An inspection report after the last inspection from March 26-30, 2012, indicated that they are satisfied with all the outstanding action points that Dr. Reddy's has submitted.

With the satisfactory closure of observations in the warning letter and the lifting of the import alert, Dr. Reddy's can now start importing products to the US from this facility.

The Mexico facility produces intermediates and active pharmaceutical ingredients.