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Biocon receives 12 USFDA observations for Malaysia unit

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The company will respond to the FDA with a Corrective and Preventive Action Plan



Indian biopharmaceutical company Biocon has announced that its Sdn Bhd's Insulin Glargine Drug Substance, Drug Product and Device assembly facilities in Malaysia underwent a pre-approval inspection by the U.S. FDA between June 24 and July 5, 2019. The inspection across these 3 units concluded with 12 observations issued on the Form 483.

The company will respond to the FDA with a Corrective and Preventive Action Plan and are confident of addressing these observations expeditiously. Biocon does not expect any change to its commercialization plans for Insulin glargine in the U.S. Biocon remains committed to global standards of Quality and Compliance.