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Biocon receives USFDA's Complete Response Letter for insulin glargine

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CRL has been issued pending completion of the corrective and preventive actions (CAPAs) submitted to the US FDA



Biocon said that the US Food and Drug Administration (US FDA) has issued a complete response letter (CRL) for the New Drug Application (NDA) for insulin glargine filed by partner Mylan.

The company said in statement that, the CRL has been issued pending completion of the corrective and preventive actions (CAPAs) submitted to the US FDA in response to the observations made at the conclusion of the pre-approval inspection of insulin manufacturing facility in Malaysia in June 2019.

The company added that CRL did not identify any outstanding scientific issues with the application. We remain confident of the quality of our application and do not anticipate any impact of this CRL on the commercial launch timing of our Insulin glargine in the US.

"We remain committed to global standards of quality & compliance and are working closely with our Partner and the regulator to complete these CAPAs to the satisfaction of the US FDA," added Biocon.

Biocon also declared that The US Food and Drug Administration conducted a current good manufacturing practice (cGMP) inspection at one of biologics drug product facilities in Bengaluru from August 22 to August 30, 2019.

The inspection concluded with four observations which it believe will not impact supplies from this facility.We are confident of addressing these observations through a corrective and preventive action plan in a timely manner." The company said in statement.