



Biocon Limited
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CIN : L24234KA1978PLC003417

www.biocon.com

BIO/SECL/AJ/2023-24/97

October 7, 2023

To The Manager, BSE Limited Department of Corporate Services Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001	To The Manager, National Stock Exchange of India Limited Corporate Communication Department Exchange Plaza, Bandra Kurla Complex Mumbai – 400 050
Scrip Code - 532523	Scrip Symbol - Biocon

Subject: Company Statement

Dear Sir/Madam,

Please find enclosed Company Statement w.r.t. '**Biocon Biologics Receives Complete Response Letter from US FDA for Biosimilar Insulin Aspart.**'

The above information will also be available on the website of the Company at www.biocon.com.

Kindly take the same on record and acknowledge.

Thanking You,

Yours faithfully,

For **Biocon Limited**

Mayank Verma
Company Secretary and Compliance Officer
Membership No.: ACS 18776

Encl: Company Statement

NOTIFICATION TO STOCK EXCHANGE

COMPANY STATEMENT

Biocon Biologics Receives Complete Response Letter from US FDA for Biosimilar Insulin Aspart

Bengaluru, Karnataka, India, October 7, 2023

“The U.S. Food and Drug Administration (US FDA) has issued a Complete Response Letter (CRL) for the Biologics License Application (BLA) for Insulin Aspart. The CRL did not identify any outstanding scientific issues with the product. The CRL references the requirement for a satisfactory resolution of deficiencies from the pre-approval inspection (PAI) of our Malaysia facility for Insulin Aspart, held in August 2022.

The Company had submitted a comprehensive Corrective and Preventive Action (CAPA) plan in September 2022, that the agency found to be adequate and indicated that it would require a re-inspection of the Malaysia facility, prior to the approval of the application.

In February 2023, the Company submitted a report from an independent third-party consultant, providing evidence of CAPA completion and effectiveness. However, the PAI re-inspection was not scheduled prior to the goal date of October 6, 2023.”

“The Company will continue to engage with the US FDA for an expeditious resolution and approval of its biosimilar Insulin Aspart application.

This decision has no impact on the manufacturing or distribution of the Company’s existing commercial portfolio. Biocon Biologics is committed to bringing high-quality and affordable medicines to the United States.” – *Company Spokesperson*

For more information: seema.ahuja@biocon.com