



No: 2017/SEC/OCT/125

October 10, 2017

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NSE - Symbol - BIOCON

BSE - Scrip code - 532523

Dear Sir/Madam

Sub: US FDA Issues Complete Response Letter for Proposed Biosimilar Pegfilgrastim

Please find below the Company's statement on the subject matter.

The U.S. Food and Drug Administration has issued a Complete Response Letter (CRL) for Mylan's Biologics License Application (BLA) for MYL-1401H, a proposed biosimilar pegfilgrastim. This product is a part of the biosimilars portfolio being developed jointly by Biocon and Mylan.

The CRL relates to the pending update of the BLA with certain CMC data from facility requalification activities post recent plant modifications. The CRL did not raise any questions on biosimilarity, pharmacokinetic/pharmacodynamic data, clinical data or immunogenicity.

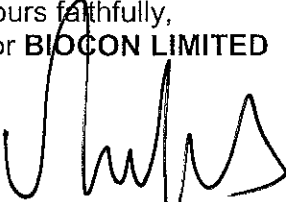
We do not expect this CRL to impact the commercial launch timing of biosimilar pegfilgrastim in the US. We are committed to working with the agency to resolve the issues stated in the CRL expeditiously.

- *Company Spokesperson*

Kindly take on record the same.

Thanking You,

Yours faithfully,
For **BIOCON LIMITED**


Rajiv Balakrishnan
Company Secretary