PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Financial Express, Delhi
Fri, 17 Feb 2017, Page 6
Width: 41.49 cms, Height: 45.38 cms, a3, Ref: 9.2017-02-17.69

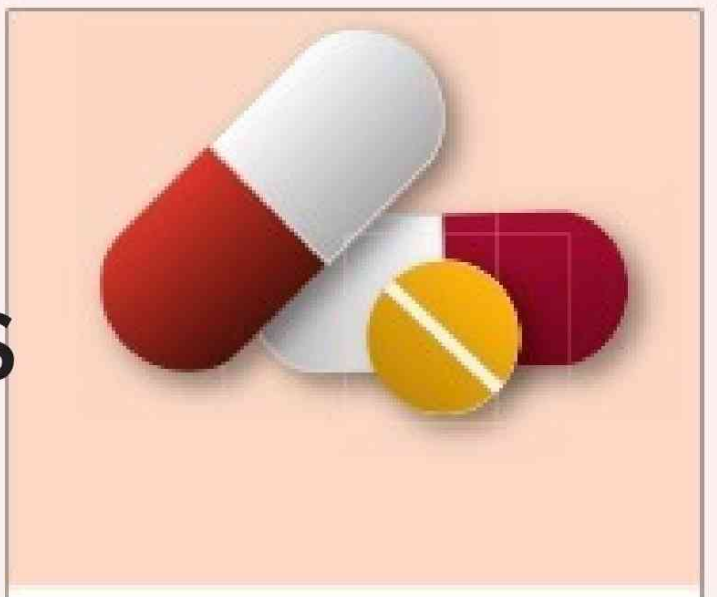
USFDA accepts Biocon's drug application for review

fe Bureau

Bengaluru, Feb 16: In what could be a significant step towards entering regulated markets, Biocon and Mylan on Thursday announced that the US Food and Drug Administration (USFDA) has accepted for review their application for proposed biosimilar Pegfilgrastim, which is used to treat cancer patients undergoing chemotherapy.

Mylan's Biologics Licence Application (BLA) for MYL-1401H, a proposed biosimilar to Neulasta (pegfilgrastim), was submitted through the 351(k) pathway, Biocon said. The proposed biosimilar to Neulasta is used to reduce the duration of neutropenia (low count of neutrophils, a type of white blood cells) and the incidence of fever associated with neutropenia in adult patients treated with chemotherapy in certain types of cancer. The FDA goal date set under the Biosimilar User Fee Act (BsUFA) is October 9, 2017, Biocon said.

crore units



Once approved, proposed biosimilar pegfilgrastim will complement Mylan's broad oncology portfolio

"We are proud of the FDA acceptance of our BLA for proposed biosimilar pegfilgrastim. This is the second BLA accepted for review by the FDA as part of the Mylan and Biocon partnership within the past two months. The milestone builds upon the acceptance of regulatory filings for proposed biosimilar pegfilgrastim in Europe, Australia, and Canada, and reinforces our dedication and commitment to establishing a global platform for this product," Mylan president Rajiv Malik said.

Once approved, proposed biosimilar pegfilgrastim will complement Mylan's broad oncology portfolio focused on expanding access to more affordable treatments for multiple types of cancer, he said.

"Once approved, our proposed biosimilar pegfilgrastim will provide a high quality alternative to branded pegfilgrastim (Neulasta) for cancer patients during cytotoxic chemotherapy. It will expand our oncology portfolio and further enable us to fulfil our promise of making cancer-care affordable and accessible for patients across the globe," Arun Chandavarkar, CEO and joint MD, Biocon, said.