New Drug Approvals

Generic Name (Trade Nameâ€"Company)	**Uses**/Notes
June 5, 2018	
Pegfilgrastim-jmdb ***(Fulphila—Mylan GmbH)*** **First pegfilgrastim biosimilar helps reduce the risk of infection during cancer treatment**	FDA approved pegfilgrastim-jmdb as the first biosimilar to pegfilgrastim (Neulasta) to decrease the chance of infection as suggested by febrile neutropenia in patients with nonmyeloid (non–bone marrow) cancer who are receiving myelosuppressive chemotherapy that has a clinically significant incidence of febrile neutropenia. FDA's approval of the new biosimilar was based on a review of evidence that included extensive structural and functional characterization, animal study data, human pharmacokinetic and pharmacodynamic data, clinical immunogenicity data, and other clinical safety and effectiveness data that demonstrates pegfilgrastim-jmdb is biosimilar to pegfilgrastim. It has been approved as a biosimilar, not as an interchangeable product. The most common adverse effects are bone pain and pain in extremities. Patients with a history of serious allergic reactions to human granulocyte colony–stimulating factors such as pegfilgrastim or filgrastim products should not take the new biosimilar. Serious adverse effects from treatment include rupture of the spleen, acute respiratory distress syndrome, serious allergic reactions including anaphylaxis, acute inflammation of the kidney, an abnormally high level of white blood cells, capillary leak syndrome, and the potential for tumor growth. Fatal sickle cell crises also have occurred.

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