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## FDA Accepts the First Biosimilar Application under the BPCIA

Sandoz announced today that the FDA accepted its Biologics License Application (BLA) for filgrastim. This marks the first acceptance of a biosimilars application (351(k)) filed under the pathway created by the Biologics Price Competition and Innovation Act of 2009 (BPCIA).

Filgrastim is an analog of granulocyte colony-stimulating factor (G-CSF). The reference product – Amgen's NEUPOGEN® – is indicated to decrease the incidence of infection in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia. NEUPOGEN® is a small protein, containing 175 amino acids, that is manufactured by recombinant DNA technology in bacteria.

As defined by the BPCIA, a biosimilar biologic is a biological product that is highly similar to the reference product and there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. The BPCIA also provides for approval of a biosimilar biologic under the heightened standard of interchangeability. To be approved as an interchangeable, in addition to the requirements to demonstrate biosimilarity, the biosimilar product must also produce the same clinical result as the reference product in any given patient, and the risk in terms of safety or diminished efficacy between alternating or switching between use of the reference product and the biosimilar is not greater than the risk of continuation with the reference product. Interchangeability is considered the "holy grail" for biosimilars because it provides a period of exclusivity for the first approved interchangeable biologic.

It is unclear whether Sandoz is seeking approval of their biosimilar filgrastim as a biosimilar or interchangeable. Regardless of the type of approval sought, FDA will now review the application in view of the draft guidance documents they have released pertaining to scientific, quality, and clinical pharmacology considerations. As has happened in a number of recent circumstances, FDA is once again operating under a published Draft Guidance and acceptance of the Sandoz application comes prior to issuance of any final guidance related to the biosimilar approval process. However, Sandoz and other biosimilar applicants have likely had informal meetings with FDA for quite some time to discuss the type of data needed for approval.

Importantly, acceptance of the application also triggers the patent exchange provisions of the BPCIA. As the first requirement, Sandoz must provide a copy of its BLA to Amgen within 20 days. During the next approximately 6-7 months, Amgen and Sandoz will identify patents to be litigated. The patent exchange provision is meant to provide clarity for the biosimilar applicant on the identity and number of patents that will be litigated.

Although it has taken four years for the first 351(k) application to be filed, acceptance of Sandoz's application is the first step towards approval of the first biosimilar biologic in the United States.

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