FDA Approves First Interchangeable Biosimilar Product

Related Services

Intellectual Property

Patents

CLIENT ALERT | 7.29.2021

On July 28, the U.S. Food and Drug Administration (FDA) approved the first-ever interchangeable biosimilar product.

Viartis Inc. – formerly Mylan – and Biocon Biologics' Semglee® (insulin glargine-yfgn) was first approved by the FDA on June 11, 2020 as an insulin injection product to help improve glycemic control in adult and pediatric patients with Type 1 diabetes mellitus and in adults with Type 2 diabetes. However, it was not approved as an interchangeable biosimilar insulin product with the reference product Lantus® (insulin glargine) at that time.

Now, with the FDA's July 28 approval, Semglee® (insulin glargine-yfgn) is considered a biological product that is highly similar to, and has no clinically meaningful differences from, the reference product Lantus® (insulin glargine). The FDA's approval signifies that both products share no clinically meaningful differences in terms of safety, purity, and potency. Because Semglee® (insulin glargine-yfgn) is now an interchangeable biosimilar product, it may be substituted for the reference product Lantus® (insulin glargine) at any pharmacy without the intervention of the patient's health care provider. 42 USC §262(i)(3). Moreover, as Semglee® (insulin glargine-yfgn) was approved as the first interchangeable biosimilar specifically for the treatment of diabetes, Viartis Inc. and Biocon Biologics are eligible to a one year exclusivity before the FDA can approve another biosimilar interchangeable to Lantus® (insulin glargine). 42 USC §262(k)(6).

It is noteworthy that the FDA has approved a number of biosimilars, but none have previously received the highly desired "interchangeable" status, perhaps for a number of reasons, including patent protection hurdles. Acting FDA Commissioner Janet Woodstock, M.D. called the approval of Semglee® (insulin glargine-yfgn) as an interchangeable biosimilar "momentous," paving the way to the reduction in health care costs.