

FDA approves cheaper version of top-selling diabetes drug

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Federal health officials have approved a cheaper version of the world's top-selling insulin from Sanofi for millions of U.S. patients with diabetes.

The Food and Drug Administration approved a new form of Sanofi's pen-like injector, Lantus, from drugmakers Eli Lilly and Co. and Boehringer Ingelheim.

Those companies received tentative FDA approval for their drug, called Basaglar, in August 2014. But the launch was delayed by a patent dispute with Sanofi. The three drugmakers reached an agreement in September allowing the launch of the new drug.

Insulin is a hormone that is crucial for controlling sugar levels in the blood. People with diabetes either do not produce enough insulin or cannot properly use it.

Lantus is the top product for Sanofi and the third best-selling medicine in the world by revenue. British research firm GlobalData says Lantus had sales of \$12.4 billion in 2014.

The FDA said Wednesday it approved Basaglar based on data showing it is safe and effective and works similarly to Lantus. The most common side effects reported in company trials included allergic reactions, injection site reactions, itching, rash and weight gain.

Lilly and Boehringer already sell Basaglar in several European countries. The two companies have not set a U.S. price yet, but it likely will be significantly lower than the price for the original product.

The diabetes market is fiercely competitive, and top rivals recently have been introducing new products across several classes of diabetes pills, as well as easier-to-use insulins.

About 95 percent of the estimated 29 million Americans with diabetes have Type 2 diabetes, which is often linked to obesity and a sedentary lifestyle. Type 1 diabetes, often called insulin-dependent diabetes, typically is diagnosed in childhood or adolescence, while Type 2 diabetes typically strikes in middle age.

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