FDA: Insulin among drugs transitioned to biological products

March 25 2020

Insulin and other biologic drugs, such as human growth hormone, have

now transitioned to being regulated as biological products, providing a new pathway for approval of biosimilars and interchangeable versions of these products and introducing competition into the market, the U.S. Food and Drug Administration announced Monday.

"Today is a historic day and a landmark moment for patients with diabetes and other serious medical conditions," the FDA wrote in a statement. "The availability of safe and effective biosimilar and interchangeable versions of these treatments, including insulin, is expected to increase patient access, adding more choices and potentially reducing costs of these vital therapies."

Historically, under the Federal Food, Drug, and Cosmetic (FD&C) Act, this small subset of "biological products" were approved as drugs. With the transition to being regulated as biological products, they can serve as reference products, and it will now be possible for manufacturers to submit for approval biosimilar and interchangeable products that reference insulin and these other transitioned biological products, effectively eliminating the limitations on the scope of data that could be used in a generic drug application. This change helps to ensure competition in the market and could make medications more affordable for patients.

The drugs included in this regulatory transition include those used to treat, diagnose, and prevent diabetes, respiratory distress syndrome, fertility conditions, Cushing syndrome, deep vein thrombosis, Gaucher disease, and others. Under the Biologics Price Competition and Innovation Act of 2009, Congress created a 10-year timeline for stakeholders to prepare for the regulatory transition of biological products historically regulated under the FD&C Act. Now that these 10 years are up, the FDA can start reviewing applications for proposed biosimilars to these transitioned biological products. FDA analyses have shown that introducing just one generic on the market reduces prices by

31 to 39 percent versus before generic competition, the agency noted.

"We stand ready to review incoming applications from industry," the FDA wrote in the statement. "We will also continue to work closely with those interested in producing biosimilar and interchangeable products to support efficiency in development, review and approval of these medicines."

More information: More Information