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Sandoz, a Novartis company, has announced that the US Food and Drug Administration (US FDA) has approved Zarxio (filgrastim-sndz) for all indications included in the reference product's label. Sandoz is the first company to receive approval of a biosimilar in the US through the new FDA biosimilars pathway established under the Biologics Price Competition and Innovation Act.

The approval was based on a comprehensive package of analytical, nonclinical, and clinical data, which confirmed that Zarxio is highly similar to the US-licensed reference product. The approval of Zarxio follows the unanimous positive vote in January by the Oncologic Drugs Advisory Committee (ODAC).

"The FDA approval of Zarxio marks a significant milestone for the United States healthcare system and for patients who might suffer from neutropenia," said Ms Carol Lynch, global head of biopharmaceuticals and oncology injectables at Sandoz. She added, "As the global leader in biosimilars, we are honored to be the first company to successfully work with FDA to navigate the US biosimilar pathway and we look forward to making this high-quality biosimilar available to patients in the US."

Marketed as Zarzio outside of the US, the Sandoz biosimilar filgrastim is available in more than 60 countries worldwide, has generated over 7.5 million patient-days of exposure.