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FDA approves first biosimilar drug in US

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(HealthDay)—The U.S. Food and Drug Administration has approved Zarxio (filgrastim-sndz), the first biosimilar product approved in the United States.

Clinical studies showed Zarxio had no clinically meaningful difference in safety and effectiveness from Amgen Inc.'s Neupogen that was approved in 1991, the FDA said Friday in a news release. "Only minor differences in clinically inactive components are allowable in biosimilar products," the agency said in clarifying its definition of a biosimilar drug.

Zarxio is approved for the same indications as the already-sanctioned drug, including:

- People with cancer who are on myelosuppressive chemotherapy.
- People with acute myeloid leukemia who are on induction or consolidation chemotherapy.

- People with cancer who are having bone marrow transplant.
- People who are having autologous peripheral blood progenitor cell collection/therapy.
- People with severe chronic neutropenia.

The most common clinical side effects of Zarxio include pain in the bones and muscles, and redness, swelling and itching at the injection site. More serious adverse reactions could include spleen rupture, serious allergic reaction and acute respiratory distress syndrome, the FDA said.

Biosimilar drugs are permitted under the Biologics Price Competition and Innovation Act of 2009, part of the Affordable Care Act signed by President Barack Obama in 2010, the FDA said. Zarxio is produced by Novartis, based in Princeton, N.J.

More information: More Information

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