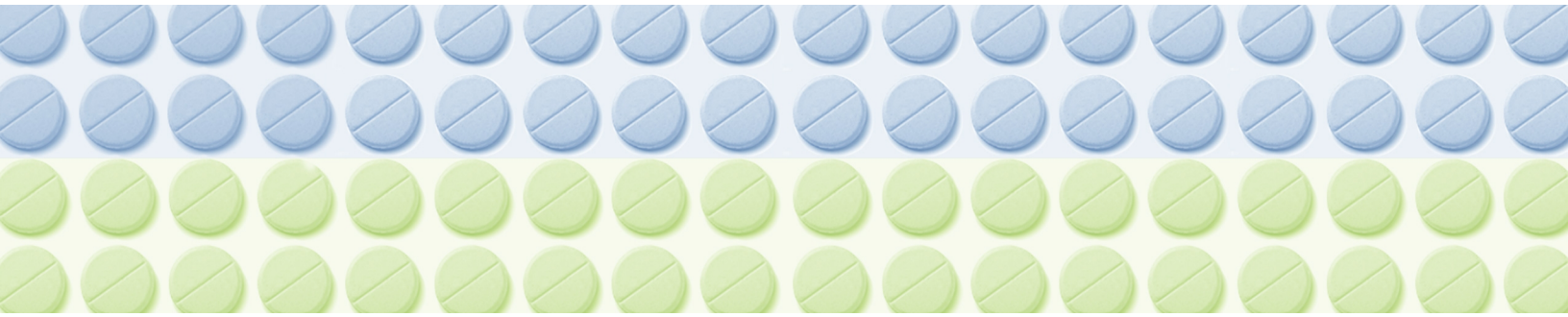

US FDA Provides First BPCIA Biosimilar Approval – Filgrastim-sndz

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The FDA issued a *press release* stating that it had approved Sandoz's filgrastim-sndz product, Zarixo. It was approved as a biosimilar of Amgen's blockbuster drug Neuopogen (filgrastim). This is significant because it is the first biosimilar approval via the *Biologics Price Competition and Innovation Act* of 2009 ("BPCIA"). The approved indications primarily relate to cancers and neutropenia (low white blood cell count). The FDA considered that filgrastim-sndz had a suitably similar mechanism of action, route of administration, dosage form and strength as the Neupogen reference product. The products are not considered interchangeable.

The FDA also stated that the "placeholder" nonproprietary name provided for this product "should not be viewed as reflective of the agency's decision on a comprehensive naming policy for biosimilar and other biological products." So it appears that the issue of whether the FDA may permit the product to eventually be marketed as "filgrastim" is still in play.

The FDA previously approved Teva's *tbo-filgrastim* product, but this was via a biologics license application ("BLA"), which was the only route for "follow-on" biologic drug approval prior to the BPCIA. Tbo-filgrastim was therefore not approved as a biosimilar to Neupogen (filgrastim) according to the FDA. The BLA route was used for other follow-on products, such as Sandoz's Omnitrope (human growth hormone). Filgrastim biosimilars have also been on the market in Europe for several years.

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