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Amgen’s Biosimilar fails to get FDA approval

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It marks the third Herceptin biosimilar that has been stalled by the FDA but has won approval in Europe.

Singapore- Amgen, in a two-sentence announcement, said it received a complete response letter for the biosimilar of Roche’s cancer med Herceptin it developed with Allergan. It marks the third Herceptin biosimilar that has been stalled by the FDA but has won approval in Europe.

The Thousand Oaks, California-based drugmaker offered no insight into what the FDA found lacking in its version. “We will work closely with the FDA to bring this important medicine to patients in the U.S. We do not expect this to impact our U.S launch plan,” it said in the announcement.

Biosimilar makers have been hot to develop their own versions of Roche’s Herceptin, a long-in-the tooth oncology drug that still raked in $2.5 billion in U.S. sales last year and $7 billion worldwide. Mylan and partner Biocon, Pfizer and now Amgen have all had their initial applications delayed by U.S. regulators.

Mylan and Biocon won an FDA thumbs-up for their Herceptin biosimilar in December, but only after a three-month delay in which the FDA looked over some new technical data that had resulted from changes made in their manufacturing operations. When the partners got consideration of their version delayed, it looked like they would go from the front of the line to the back of the line as the FDA considered applications from other drug- makers. But the partners ended up being the first to win approval as competitors also had their versions sidelined.

These delays have allowed Roche to continue to go to the Herceptin cash machine. Despite recent approvals for biosimilars in the EU, Herceptin sales worldwide were up 3% last year to about $7 billion on higher sales in the U.S. and Brazil. While most of those sales come from the U.S., $2.7 billion, EU revenue is also significant, at $2.1 billion.