

AMGEN STATEMENT

As a leading provider of high quality biologic medicines, Amgen understands the challenges of developing and manufacturing innovative and biosimilar medicines.

Amgen appreciates the Agency's efforts on the guidelines and encourages adoption of a thorough review and approval process. The FDA's acknowledgement that determining interchangeability is scientifically difficult at this time is important. Patient safety does not stop at approval and Amgen believes that post-approval activities, including ongoing monitoring, are essential to patient safety.

After fully evaluating the guidance, Amgen looks forward to contributing to the public comment process and working with the Agency as it develops an approval process that ensures safe and effective biosimilars.

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