

# Regulatory interchangeability designation in the US

**The FDA's determination of biosimilar medicines being interchangeable does not represent a higher standard of product quality\*.**



All approved biosimilar medicines in the US meet the FDA's requirements, demonstrating they match their reference medicines.



**Reference  
medicine**

**With no clinically meaningful differences in terms of safety, efficacy, and quality**

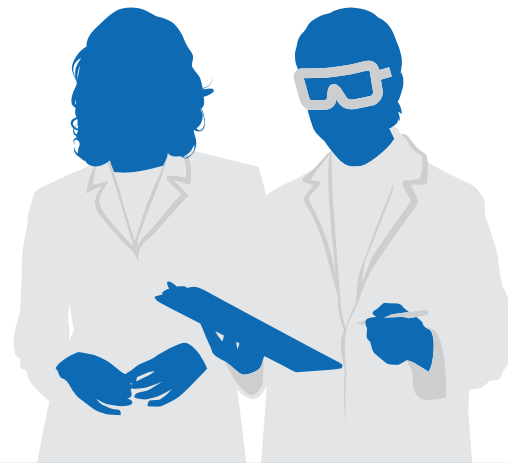


**Biosimilar**



**Interchangeability designation does not represent a higher standard**

**SANDOZ** A Novartis  
Division



**Sandoz, a Novartis division, believes that whether an approved biosimilar is designated interchangeable or not, the risk posed by switching between the biosimilar and the reference medicine is no greater than the risk posed by using the reference medicine only.**

\* A designation of interchangeability would allow for substitution at the pharmacy level, FDA guidance has not been issued as of the effective date of this position