

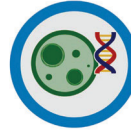
WHAT IS A BIOSIMILAR?

> A biosimilar is a biological product

FDA-approved biosimilars have been compared to an FDA-approved biologic, known as the reference product. Reference and biosimilar products are:



Large and generally complex molecules



Produced from living organisms



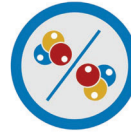
Carefully monitored to ensure consistent quality

> A biosimilar is highly similar to a reference product

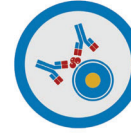
For approval, the structure and function of an approved biosimilar were compared to a reference product, looking at key characteristics such as:



Purity



Molecular structure

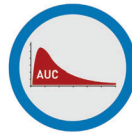


Bioactivity

The data from these comparisons must show that the biosimilar is highly similar to the reference product.

> A biosimilar has no clinically meaningful differences from a reference product

Studies were performed to show that biosimilars have no clinically meaningful differences in safety, purity, or potency (safety and effectiveness) compared to the reference product:



Pharmacokinetic and, if needed, pharmacodynamic studies



Immunogenicity assessment



Additional clinical studies as needed

Studies may be done independently or combined.

> A biosimilar is approved by FDA after rigorous evaluation and testing by the applicant

Prescribers and patients should have no concerns about using these medications instead of reference products because biosimilars:



Meet FDA's rigorous standards for approval



Are manufactured in FDA-licensed facilities



Are tracked as part of post-market surveillance to ensure continued safety