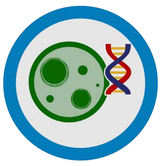
WHAT IS A **BIOSIMILAR?**

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



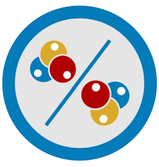
Produced from living organisms

Carefully monitored to ensure consistent quality

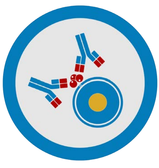
A biosimilar is highly similar to a reference product

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

Visit **www.FDA.gov** to learn more about biosimilars.

FDA U.S. FOOD & DRUG ADMINISTRATION