AMGEN BIOSIMILARS

# UNDERSTANDING BIOSIMILARS: HOW ARE THEY REGULATED IN THE U.S.?

When Congress first passed a law creating a pathway for the approval and regulation of biosimilars in 2010, **the U.S. Food and Drug Administration (FDA) established a rigorous, science-based process for the review and approval of biosimilars.**

Since then, the FDA has continued to review and optimize this process to ensure that patients and providers can rely on the safety, effectiveness, and quality of every biosimilar brought to market.

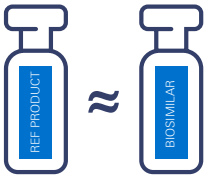
## TAKE A CLOSER LOOK:

To support approval by FDA, manufacturers must show that a biosimilar is **highly similar** in structure and function to its reference biologic through **several rounds of testing and review.**[1]

The manufacturer must also compare the biosimilar and reference biologic to show there are **no clinically meaningful differences** between the two products.[2]

Manufacturers analyze the characteristics of the biosimilar, such as purity, chemical identity, and bioactivity, to make sure it meets **FDA standards for safety and effectiveness.**[1]

Biosimilars that undergo additional evaluation and meet additional specific criteria may be designated by FDA as **interchangeable** with their reference products.




**This robust evaluation process means that patients, physicians, payers, and employers can be just as confident in the safety and effectiveness of a biosimilar as they would be in the originator biologic.**

**Please find additional information on AmgenBiosimilars.com and the FDA website.**

USA-CBU-81016

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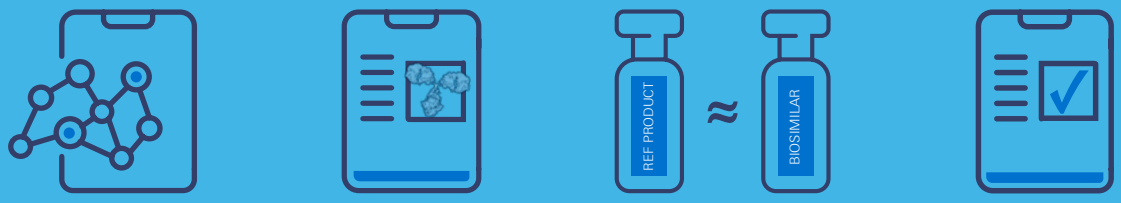
## DEFINITIONS

- **PURITY** means relative freedom from extraneous matter in the finished product, whether or not harmful to the recipient or deleterious to the product. Purity includes, but is not limited to, relative freedom from residual moisture or other volatile substances and pyrogenic substances.[3]
- **CHEMICAL IDENTITY** refers to the structural characteristics of a product. Any differences in quality attributes between a biosimilar and its reference product must be justified and shown not to impact on the safety and efficacy of the biosimilar by scientific investigations including pre-approval nonclinical and/or clinical studies.[4]
- **BIOACTIVITY** describes the effects of a drug on living matter.[5]
- **AN INTERCHANGEABLE PRODUCT** is a biosimilar that meets additional requirements outlined by the law.[2] An interchangeable product may be substituted for the reference product without the involvement of the prescriber, consistent with state pharmacy laws.




## REFERENCES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