



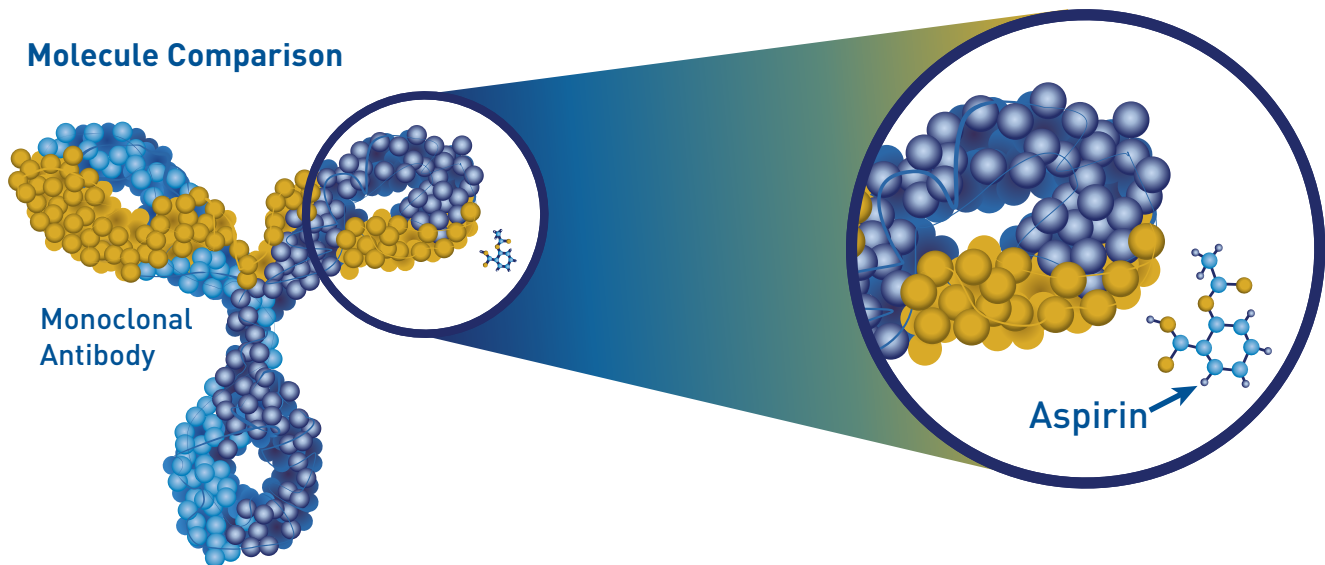
Overview of Biosimilar Products




Biosimilars are safe and effective biological medications for treating many illnesses, including chronic skin diseases, such as psoriasis; inflammatory bowel diseases, such as Crohn's disease and ulcerative colitis; arthritis; kidney conditions; diabetes; and cancer. These medications can provide more treatment options and potentially reduce costs for patients.

Biosimilars Are Biological Products

- Biological products, or biologics, are generally large, complex molecules that are made from living sources such as bacteria, yeast, and animal cells. On the other hand, drugs made from chemicals are smaller molecules and easier to copy.
- Because they generally come from living organisms, biologics inherently contain many slight variations from batch to batch, and their structures are generally more complex than those of other medications. As a result, biologics are often more complicated to purify, process, and manufacture.
- There are many types of biologics approved for use in the United States, including therapeutic proteins; vaccines; blood, blood components, and their derivatives; allergenic products; and monoclonal antibodies.

Molecule Comparison



REFERENCE PRODUCT	BIOSIMILAR	INTERCHANGEABLE PRODUCT
 <p>Original FDA-approved biological product.</p> <hr/> <p>Prescribed by a provider.</p>	 <p>Highly similar and with no clinically meaningful differences when compared to the reference product.</p> <hr/> <p>Prescribed by a provider.</p>	 <p>Highly similar and with no clinically meaningful differences when compared to the reference product.</p> <p>The application includes additional data and information about the impact of switching or alternating between the product and the reference product.</p> <hr/> <p>May be substituted at the pharmacy without the intervention of the prescribing provider.</p>

Biosimilars Have the Same Expected Benefits and Risks as Their Reference Products

- A biosimilar has no clinically meaningful differences from an existing FDA-approved biologic, called a reference product.
- Biosimilars are made with the same types of living sources, are given the same way, and have the same strength, dosage, treatment benefits, and potential side effects as the reference product.
- A biosimilar may be used in patients who have previously been treated with the reference product (treatment-experienced), as well as in patients who have not previously received the reference product (treatment-naïve).
- Biosimilars are like generic drugs in some ways, because both are compared to brand-name drugs and may offer patients more affordable treatment options. The main difference between biosimilars and generic drugs is that the active ingredients of generic drugs are generally smaller, simpler, and more straightforward to copy. Biologics generally cannot be copied exactly, because the products usually contain a mix of many slight variations of a protein, and this mix is never exactly the same in each dose or batch of the product. For this reason, biosimilar manufacturers submit data showing that their products have similar variations compared to the brand-name biologics and that their products have no clinically meaningful differences in terms of safety and effectiveness.

The availability of FDA-approved biosimilar and interchangeable products can provide more treatment options for patients, increase access to lifesaving medications, and potentially lower health care costs through competition.

Explore FDA’s biosimilar resources for health care professionals at www.fda.gov/biosimilars.

Biosimilars Are Approved by FDA After Rigorous Evaluation

- All FDA-approved biologics undergo a rigorous evaluation to ensure their safety, effectiveness, and quality.
- A reference product is approved in a standalone application that must contain data to demonstrate its safety and effectiveness.
- A proposed biosimilar is compared to and evaluated against a reference product to verify that the biosimilar has no clinically meaningful differences in terms of safety and effectiveness.
- The approval process provides assurance that biosimilars provide the same treatment benefits as their respective reference products.

Some Biosimilars May Be Approved for Interchangeability

- An interchangeable product is a biosimilar that a pharmacist may substitute for a reference product without consulting the prescriber, depending on state pharmacy laws.
- FDA does not approve a product as interchangeable unless a company specifically seeks an interchangeability determination.
- Patients and health care providers do not need to wait for a biosimilar product to “become” an interchangeable product. Biosimilars are as safe and effective as the reference product they were compared to.