



Prescribing Biosimilar Products

Can biosimilars be substituted for reference products by pharmacists?

When FDA carries out a scientific review of a proposed biosimilar, the evaluation does not include a determination of whether the biosimilar is interchangeable with the reference product and whether the biosimilar can be substituted for the reference product at the pharmacy. Substitution of a biosimilar for a reference product is a matter of state pharmacy law and is a decision that is generally outside of FDA's regulatory role.

Many states have laws that address substitution of biological products at the pharmacy level. It is important to note that pharmacy practices vary from state to state.

What is the difference between receiving a reference product and a biosimilar product?

Patients and their physicians can expect that there will be no clinically meaningful differences between taking a reference product and a biosimilar when these products are used as intended. All reference products and biosimilar products meet FDA's rigorous standards for approval for the indications (medical conditions) described in product labeling. Once a biosimilar has been approved by FDA, patients and health care providers can be assured of the safety and effectiveness of the biosimilar, just as they would for the reference product.

Are biosimilars approved for all the same indications as the reference product?

Biosimilar products may be approved for all or a subset of the same indications as the reference product. Biosimilars may have fewer indications than the reference product if, for example, a reference product has unexpired exclusivity for an indication that prevents other manufacturers from obtaining approval for that particular indication. Health care prescribers should review the specific product labeling (prescribing information) and approved indications to determine the most appropriate product for their patient.

	Meets FDA's rigorous approval standards	Safe option for patients	Effective option for patients
			
			

Can a biosimilar product be used in patients who have previously been treated with the reference product?

Yes, biosimilars can 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). Before approval of the biosimilar product, FDA may request additional data that looks at safety information for treatment-experienced patients who undergo a single transition (single switch) from a reference product to a biosimilar product.

Where can you find more information about biosimilar products?

FDA's "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations," known as the "Purple Book," is an online resource for health care professionals and patients to locate information about approved biological products. The Purple Book provides information about whether a biological product is a reference product, biosimilar, or interchangeable product.

Product-specific information, including a summary of FDA's review of the data that were used to support approval of a biological product, can be found at the Drugs@FDA website. You can also visit www.fda.gov/biosimilars.