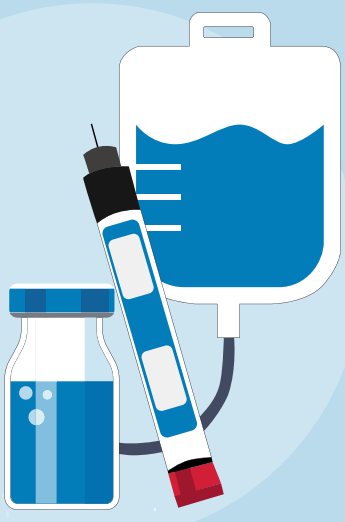
U.S. FOOD & DRUG ADMINISTRATION

Biosimilar Basics

Biosimilars are a type of biologic medication that is **safe and effective** for treating many illnesses, such as chronic skin and bowel diseases, arthritis, diabetes, kidney conditions, macular degeneration, and some cancers.



Most **biologic medications** have minor differences between batches because they generally are made from living sources (such as animal cells, bacteria or yeast). Biologics are **developed using advanced science** and usually given by injection.

Biosimilars are **FDA-approved** medications that are very similar, but not identical, to another medication — the original biologic already approved by FDA.

A biosimilar and its original biologic are made from the same types of sources — and **have the same treatment risks and benefits.**

Biosimilar and Original Biologic

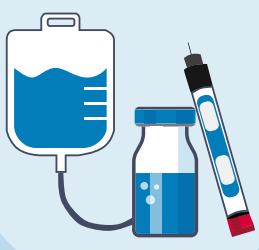
- ☑ **Same benefits**
- ☑ **Same potential side effects**
- ☑ **Same strength and dosage**
- ☑ **Given the same way**

Biosimilars can be made by multiple companies which may lower their cost — **similar to generic drugs.** Biosimilars are like generics in some ways but different in others.

Biosimilars
Generally made from living sources
Require a specialized process to produce
Very similar, but not identical, to original biologics
Usually less expensive than original biologics

Generics
Generally made from chemicals
Have a simpler process to copy
Copy of brand-name drugs
Usually less expensive than brand-name drugs

Biosimilars may provide patients with **more access** to important treatments and an opportunity to **save money.**



More options

Lower costs

Biosimilars are approved by FDA after a **careful review** of data, studies, and tests conducted by companies.

FDA monitors the **safety** and **effectiveness** of all medications after their approval.

Check for medication quality during production

Review patient safety reports

To learn more, visit
www.FDA.gov/biosimilars