A biosimilar is a biologic medicine that is highly similar to a brand name biologic medicine.

A biologic drug, or biologic, is a drug made from proteins or pieces of proteins (either natural or artificial). Unlike other drugs, biologic drugs must be made in a living system, such as yeast, bacteria, or animal cells.

A biosimilar drug, or biosimilar, is a medicine that is very close in structure and function to a biologic drug.

For some brand name biologic drugs, one or more biosimilars are available. A biosimilar drug has a structure that is highly similar to, but not exactly the same, as a brand name biologic drug. A biosimilar behaves in much the same way so that there are “no meaningful differences” between it and its brand name biologic. This means that the biosimilar drug is also considered both safe and effective as the biologic drug. Both come from living systems.

As of October 2021, 31 biosimilars have received FDA-approval for several indications, including:

- Psoriasis
- Inflammatory Bowel Disease
- Diabetes
- Rheumatoid Arthritis
- Kidney Conditions
- Cancer

A biosimilar drug is a little like a generic version of a biologic drug. Both are tested and compared in clinical trials to a brand name drug that's already FDA approved. Both go through a thorough but shortened FDA review process compared to their brand name drugs. Both are as safe and effective as their brand name drugs, and both might be less expensive treatment options than their brand name drugs.

However, there are important differences. A biosimilar comes from the same natural source and is the same in certain ways as its brand name biologic drug, while a generic is an exact chemical copy of its brand name drug. Unlike a generic drug, a biosimilar drug is highly similar to its brand name drug, but not be an exact copy of it. Therefore, the FDA often needs more information from biosimilar studies than it needs from studies done on a generic drug.

What is an interchangeable biosimilar? When a generic drug is approved by the FDA, it's usually automatically interchangeable with its brand name drug. Because it is an exact chemical copy, there is no additional information needed by the FDA to show a generic drug is a safe and effective substitute for its brand name drug. This means a prescription written for a brand name drug can usually be filled using a generic drug without notifying the provider who wrote the prescription.

While all biosimilars go through the same initial FDA approval process, and they can be used to treat a disease once they get initial approval, a biosimilar needs another, special FDA approval before it is considered interchangeable and can be substituted automatically for its brand name drug.

Where can I learn more? Speak to your healthcare provider and/or pharmacist. Additional information is available at: https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars