



## Biologics and Biosimilars: Background and Key Issues (Paperback)

By Congressional Research Service

Createspace Independent Publishing Platform, 2017. Paperback. Condition: New. Language: English . Brand New Book \*\*\*\*\* Print on Demand \*\*\*\*\*.A biological product, or biologic, is a preparation, such as a drug or a vaccine, that is made from living organisms. Compared with conventional chemical drugs, biologics are relatively large and complex molecules. They may be composed of proteins (and/or their constituent amino acids), carbohydrates (such as sugars), nucleic acids (such as DNA), or combinations of these substances. Biologics may also be cells or tissues used in transplantation. A biosimilar, sometimes referred to as a follow-on biologic, is a therapeutic drug that is similar but not structurally identical to the brand-name biologic made by a pharmaceutical or biotechnology company. In contrast, a generic chemical drug is an exact copy of a brand-name chemical drug. Because biologics are more complex than chemical drugs, both in composition and method of manufacture, biosimilars will not be exact replicas of the brand-name product, but may instead be shown to be highly similar. The Food and Drug Administration (FDA) regulates both biologics and chemical drugs. Biologics and biosimilars frequently require special handling (such as refrigeration) and processing to avoid contamination by microbes or other unwanted substances. Also,...



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