

# *Script Your Future Biosimilars Webinar*

April 2, 2024



A Campaign of the National Consumers League

# Speakers

**Shelley Skibinski, Pharm.D.,** *Project Coordinator and Purple Book Lead, FDA*

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**Robin Strongin,** *Senior Director, Health Policy, NCL - Moderator*





**U.S. FOOD & DRUG  
ADMINISTRATION**

# Biosimilars

## What You Need to Know

**National Consumers League  
Pharmacy Student Education  
April 2024**

**Shelley Skibinski, Pharm.D., *Project Coordinator and Purple Book Lead***  
**Sarah Ikenberry, M.A., *Senior Communication Advisor***  
Office of Therapeutic Biologics and Biosimilars (OTBB)  
Center for Drug Evaluation and Research (CDER)  
U.S. Food and Drug Administration (FDA)

# Biosimilars

- A biosimilar is a type of biologic medication that is safe, pure, and potent for the treatment of many chronic and severe conditions, including:



Chronic Skin Diseases



Chronic Bowel Diseases



Diabetes



Macular Degeneration



Arthritis/Osteoporosis



Kidney Conditions



Some Cancers



Multiple Sclerosis

# FDA Approved Biosimilar and Interchangeable Products\*



Product Class		Approvals
Supportive Care	Filgrastim	B B B
	Epoetin	B
	Pegfilgrastim	B B B B B B
Oncology	Rituximab	B B B
	Bevacizumab	B B B B B
	Trastuzumab	B B B B B
& Osteoporosis	Denosumab	I
Autoimmune	Infliximab	B B B B
	Etanercept	B B
	Adalimumab	B I B B I B B B B I
	Insulin Glargine	I I
	Natalizumab	B
	Tocilizumab	B B
	Ustekinumab	I
Ophthalmology	Ranibizumab	I I

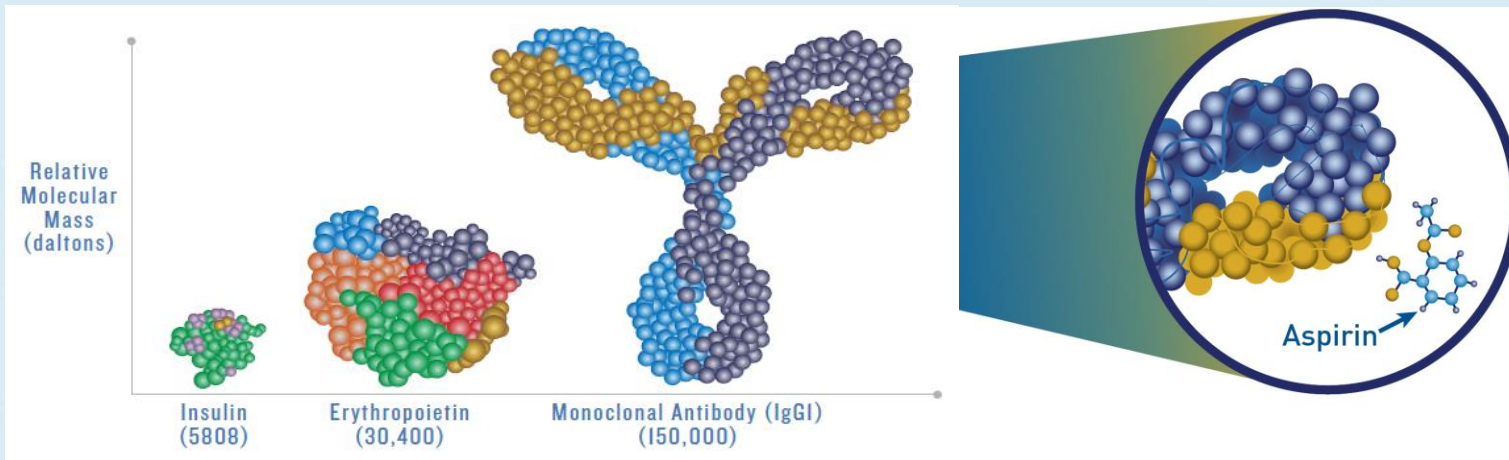
Biosimilar  
 Interchangeable Biosimilar

- **48** biosimilars approved to **15** different reference products
- **9** approved as interchangeable
- **38** marketed

\*as of March 11, 2024

# What are Biologic Medications?

- Most biologics are made from living sources, such as animal cells and microorganisms like bacteria or yeast.
- Because biologics generally come from living sources and have inherent variability, they can be more complicated to produce than drugs made from chemicals.
- Drugs made from chemicals, such as aspirin, can generally be more easily copied.



Modified from Mellstedt H, EJC Supplements II, 2013, 3,

# Key Statutory Definitions



## Reference Product

A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar product is compared (also called an original or originator product)



## Biosimilar Product

A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product



## Interchangeable Biosimilar

- Is a biosimilar
- Expected to produce the same clinical result as the reference product (RP) in any given patient
- Switching between the proposed product and the RP does not ↑ safety risks or ↓ effectiveness compared to using the RP without switching



# Biosimilars and Reference Products

- A biosimilar is highly similar, but not identical, to an reference biologic medication (also known as a reference product) that FDA has already approved.
- Biosimilars have no clinical meaningful differences from the reference biologic.
- For biosimilars to be approved by FDA, studies must show that there are no differences in the safety and effectiveness of a biosimilar and the reference product.

## **Both a biosimilar and its reference product:**

- ✓ Are made from the same types of sources (e.g., living sources)
- ✓ Provide the same benefits when treating diseases or medical conditions
- ✓ Are given at the same strength and dosage
- ✓ Are not expected to cause new or worsening side effects



# General Requirements

## > A biosimilar is highly similar to a reference product

For approval, the structure and function of an approved biosimilar were compared to a reference product, looking at key characteristics such as:



Purity



Molecular structure



Bioactivity

The data from these comparisons must show that the biosimilar is highly similar to the reference product.

## > A biosimilar has no clinically meaningful differences from a reference product

Studies were performed to show that biosimilars have no clinically meaningful differences in safety, purity, or potency (safety and effectiveness) compared to the reference product:



Pharmacokinetic and, if needed, pharmacodynamic studies



Immunogenicity assessment

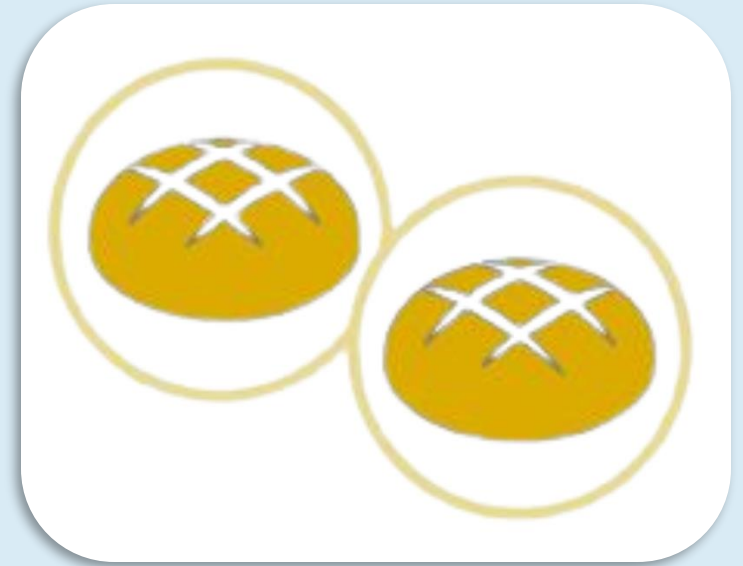


Additional clinical studies as needed

Studies may be done independently or combined.

# Why Aren't Biosimilars Identical to their Reference Product?

- Because most biologics are made from living sources, it is normal for both biosimilars and reference products to have minor differences between batches of the same medication.
- This means that biologics cannot be copied exactly, and that is why biosimilars are not identical to the reference product.
- FDA carefully reviews the differences between the reference product and the biosimilar to ensure that biosimilars are as safe and effective as the reference product.



No one loaf is an exact copy of another, but they are all the same type of bread using the same recipe.

# Are Biosimilars the Same as Generic Drugs?

- Biosimilars and generics are both versions of medications already approved by FDA.
- Biosimilars may allow multiple companies to enter the market, which may lower the cost of a particular biologic medication.
- Biosimilars may offer more affordable treatment options to more patients.

Biosimilars are like generics in some ways, but there are differences.



## Biosimilars

Generally made from living sources

Require a specialized process to produce

Very similar, but not identical, to original biologics

Faster development process using public information from original biologic approval

Usually less expensive than original biologics



## Generics

Generally made from chemicals

Have a simpler process to copy

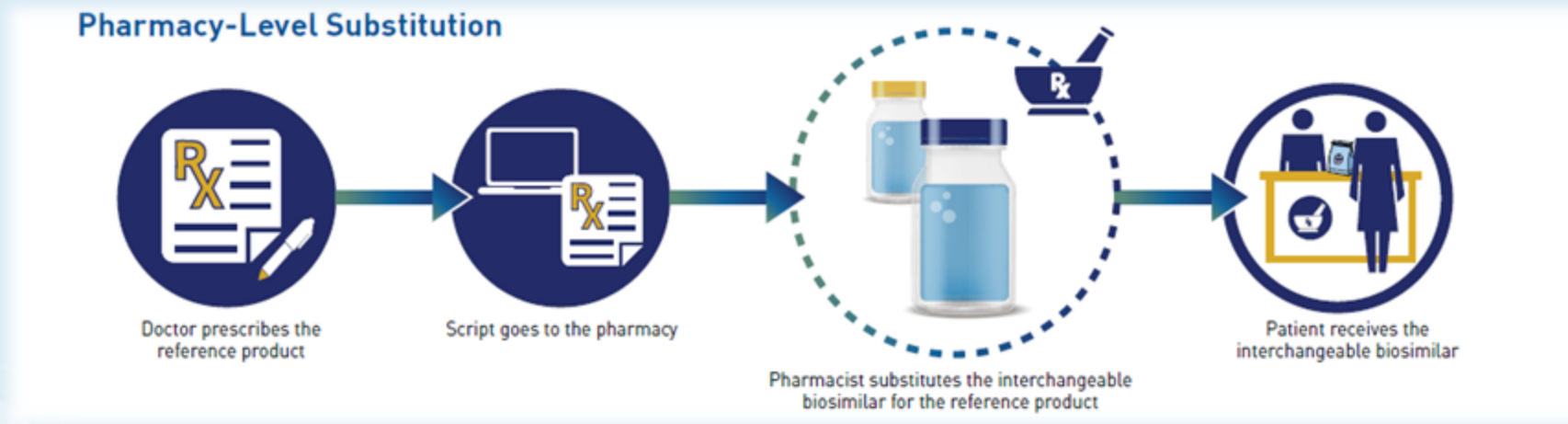
Copy of brand-name drugs

Faster development process using public information from brand-name drug approval

Usually less expensive than brand-name drugs

# What are interchangeable biosimilars?

- An interchangeable biosimilar may be substituted at the pharmacy for the reference product without the intervention of the prescribing health care provider—much like how generic drugs are routinely substituted for brand-name drugs.

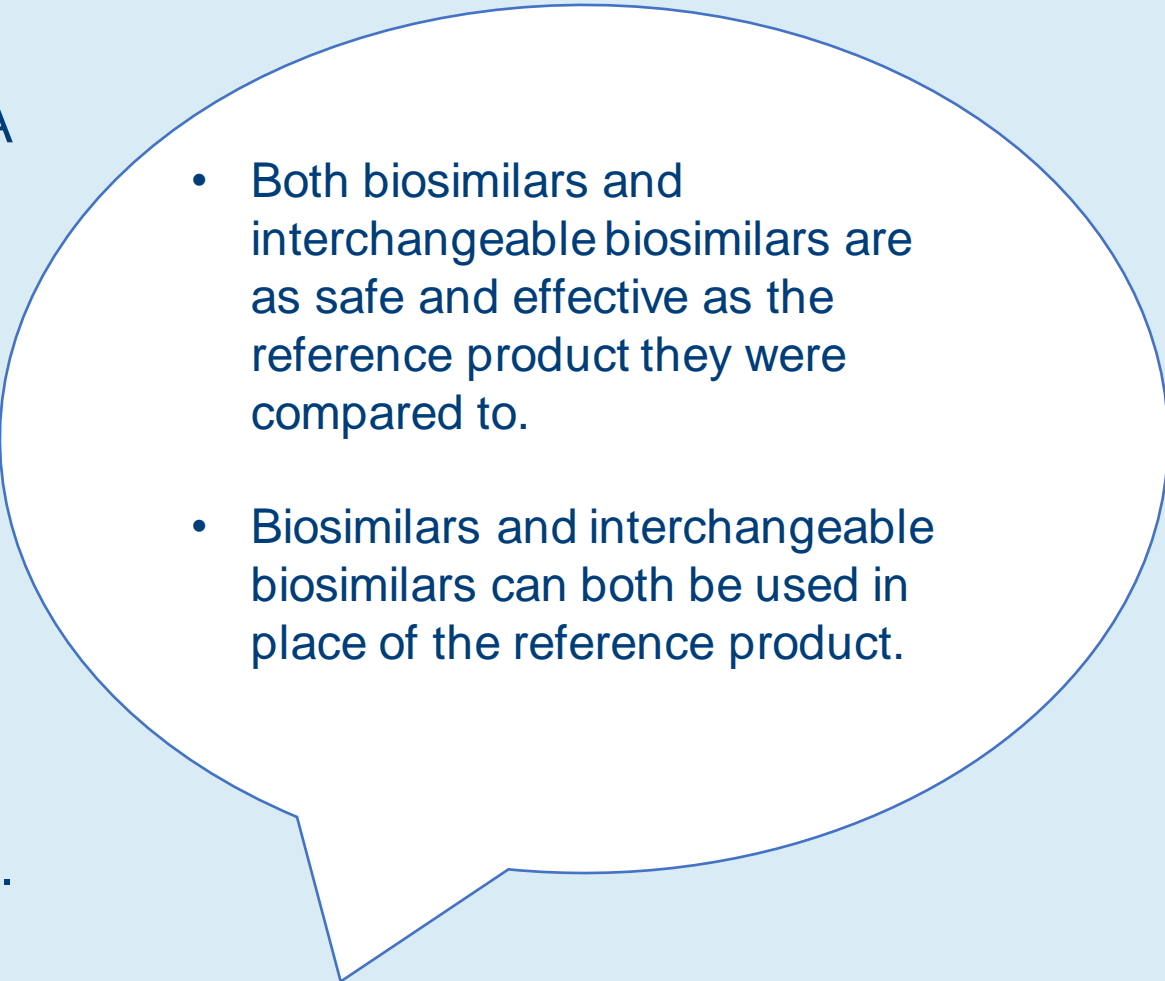


- Companies request approval as a biosimilar or an interchangeable biosimilar.






# What is the Difference between Biosimilars & Interchangeable Biosimilars?

- Both biosimilars and interchangeable biosimilars meet the same high standard of biosimilarity for FDA approval and both are as safe and effective as the reference product.
- The difference is that an interchangeable biosimilar meets additional requirements related to the potential for “pharmacy level substitution.”
- Interchangeability is only relevant to pharmacy-level substitution, which depends on state pharmacy laws.

- 
- Both biosimilars and interchangeable biosimilars are as safe and effective as the reference product they were compared to.
  - Biosimilars and interchangeable biosimilars can both be used in place of the reference product.

# Using Reference, Biosimilar, and Interchangeable Products

- As it does with all medication approvals, FDA carefully reviews the data provided by pharmaceutical companies and takes a number of steps to ensure that all biosimilars meet standards for patient use.
- Patients and health care providers *can be confident in the **safety** and **effectiveness** of a biosimilar and interchangeable product*, just as for the reference product.
- Biosimilar and interchangeable biosimilar products can be used in patients who have previously been treated with the reference product (i.e., treatment-experienced), and in patients who have not previously been treated with the reference product (i.e., treatment-naïve)

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

# Why Would a Patient Switch to a Biosimilar?

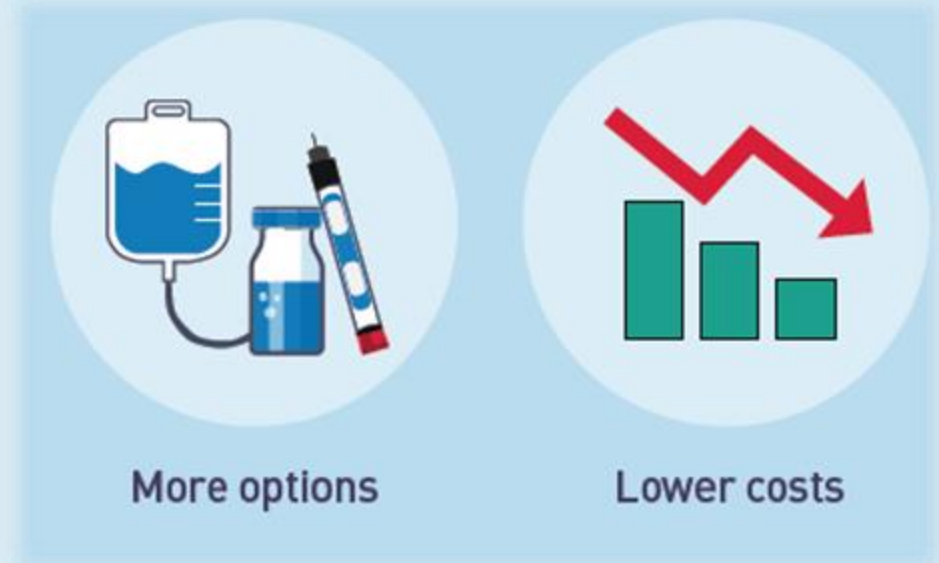
- A patient might switch to a biosimilar because of a change in insurance coverage, formulary availability, or to save money.
- Depending on state law, a pharmacist may dispense an interchangeable biosimilar, much like they would give a generic.





# Will Biosimilars Save Money?

- Similar to generic drugs, biosimilars may cost less because manufacturers rely on FDA's finding that the reference products are safe and effective. The lower cost is not a reflection of the safety or effectiveness of biosimilars.
- Because of the lower cost, biosimilars may be covered by more insurance companies and offer patients additional treatment options.
- Patients can learn more about the price of a specific biosimilar by contacting their pharmacy or insurance company.



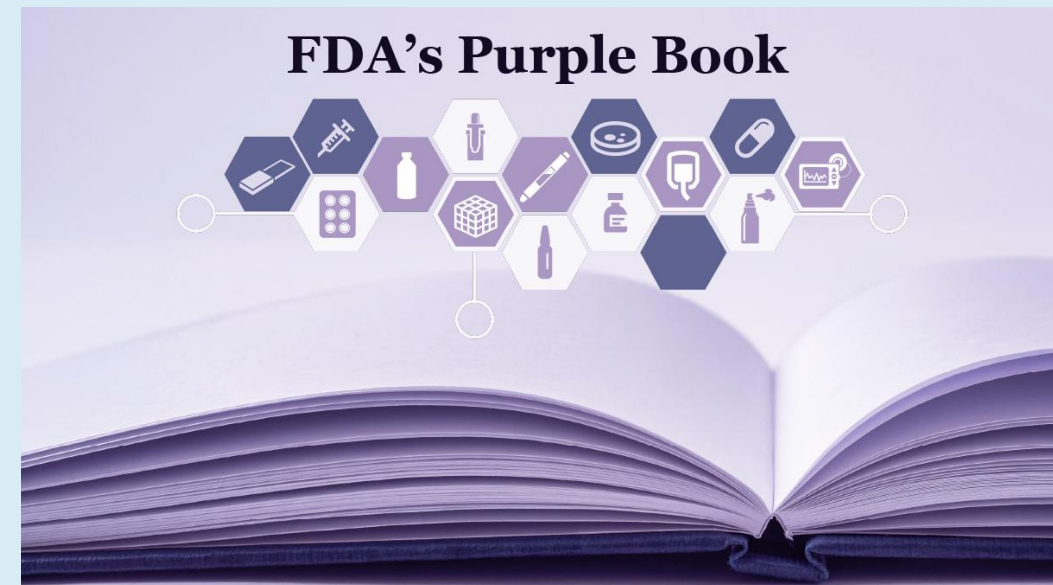
# FDA's Purple Book: Database of Licensed Biological Products

[www.PurpleBookSearch.fda.gov](http://www.PurpleBookSearch.fda.gov)

# The FDA Purple Book

Visit: <https://purplebooksearch.fda.gov>

- The database provides patients, payors, clinicians, and others with an accessible, easy-to-use online search engine with more information about FDA-approved biological products, including biosimilar and interchangeable biological products, and their reference products.
- Features tailored to different user needs, including:
  - Simple Search and Advanced Search
  - User Guide with detailed instructions
  - Auto-populated search results
  - Additional advanced search filters
  - Data download and export options
  - Product labeling links
  - Show/hide sortable data column options
  - Searchable glossary of terms



# The FDA Purple Book: Homepage & Simple Search

Visit: <https://purplebooksearch.fda.gov>

## Purple Book

### Database of Licensed Biological Products

**Purple Book Homepage**

- About Purple Book
- User Guide
- FAQs
- Patent List
- Download Purple Book Data

The Purple Book database contains information on all FDA-licensed (approved) biological products regulated by the Center for Drug Evaluation and Research (CDER), including licensed biosimilar and interchangeable products, and their reference products.

The Purple Book also contains information about all FDA-licensed allergenic, cellular and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research (CBER).

Enter a product's proprietary (brand) name or the nonproprietary (proper) name to find biological products. As you type, a list of potential results will begin to appear below the search box based on what you are typing. Click on a product from the auto-populated results list below to view the results page. The results page for your selected product will include all biological products that share a core name (*i.e.*, biosimilar, interchangeable, reference, and related biological products).

1

<b>Enbrel (etanercept)</b>	351(a)
<small>BLA Number: 103795</small>	
<b>Enbrel Mini (etanercept)</b>	351(a)
<small>BLA Number: 103795</small>	
<b>Erelzi (etanercept-szsz)</b>	351(k) Biosimilar
<small>BLA Number: 761042</small>	
<b>Erelzi Sensoready (etanercept-szsz)</b>	351(k) Biosimilar
<small>BLA Number: 761042</small>	
<b>Eticovo (etanercept-ykro)</b>	351(k) Biosimilar
<small>BLA Number: 761066</small>	

2

Advanced Search

Database last updated: May 09, 2023



# The FDA Purple Book: Simple Search Results

Visit: <https://purplebooksearch.fda.gov>

**Proprietary Name**  
Erelzi  
Erelzi Sensoready

**Proper Name**  
etanercept-szszs

**PRODUCT LABEL**

1  
2

U.S. FOOD & DRUG ADMINISTRATION

Drugs@FDA: FDA-Approved Drugs

Biosimilarity Data for BLA 751942

Drug Name	Action Registration	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
ERELZI	ETANERCEPT-ADDS	SUBCUTANEOUS	INJECTABLE, INJECTION	Prescription	None	No	No
ERELZI	ETANERCEPT-ADDS	SUBCUTANEOUS	INJECTABLE, INJECTION	Prescription	None	No	No

Action Date	Submission	Supplemental Category or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
08/11/2009	SUPPL-12	Efficacy-New Patient Population	Label (PDF)	
10/18/2010	SUPPL-10	Efficacy-New Indication	Label (PDF)	
01/08/2014	SUPPL-1	Labeling-Package Insert	Label (PDF)	
01/08/2014	SUPPL-1	Labeling-Medication Guide	Label (PDF)	
08/30/2014	CDER-1	Approval	Label (PDF)	

## Purple Book Database of Licensed Biological Products

Simple Search Results for: *Erelzi* [NEW SEARCH](#) [Navigate to Advanced Search](#)

The Simple Search Results page for the selected product includes all biological products that share a core name (i.e., biosimilar, interchangeable, reference, and related biological products).

Matching card colors indicate a biological product is biosimilar to or interchangeable with a reference product.

### Biosimilar(s)

**Proprietary Name**  
Erelzi  
Erelzi Sensoready

**Proper Name**  
etanercept-szszs

**PRODUCT LABEL**

**Proprietary Name**  
Eticovo

**Proper Name**  
etanercept-ykro

**PRODUCT LABEL**

### Interchangeable(s)

No interchangeable data at this time.

### Reference Product(s)

**Proprietary Name**  
Enbrel  
Enbrel Mini

**Proper Name**  
etanercept

**PRODUCT LABEL**

To view a list and definitions of Product Presentation Icons (e.g., , ), click [here](#). Hover over icons to view additional information.

Grayed out Product Label links indicate that there is no product label available for the product.





# The FDA Purple Book: Product Details

Visit: <https://purplebooksearch.fda.gov>

## Purple Book

### Database of Licensed Biological Products

- [Purple Book Homepage](#)
- [About Purple Book](#)
- [User Guide](#)
- [FAQs](#)
- [Patent List](#)
- [Download Purple Book Data](#)

[← RETURN TO SEARCH RESULTS](#)

**Product Details for: *Erelzi, Erelzi Sensoready***

■ Product Label
 Grayed out Product Label links indicate that there is no product label available for the product.

Product Number	Dosage Form	Route of Administration	Strength	Product Presentation	License Type <span style="font-size: 2em; color: blue;">2</span>	Proprietary Name	Status <span style="font-size: 2em; color: blue;">3</span>
001	Injection	Subcutaneous	25MG/0.5ML	Pre-Filled Syringe	351(k) Biosimilar	Erelzi	Rx
002	Injection	Subcutaneous	50MG/ML	Pre-Filled Syringe	351(k) Biosimilar	Erelzi	Rx
003	Injection	Subcutaneous	50MG/ML	Autoinjector	351(k) Biosimilar	Erelzi Sensoready	Rx

**Proper Name**  
etanercept-szzs

1

**Reference Product Proper Name**  
etanercept

1

**Reference Product Proprietary Name**  
Enbrel

**BLA Number**  
761042

**Applicant**  
Sandoz Inc.

**Original Approval Date**  
08/30/2016

**Date of First Licensure**

[← RETURN TO SEARCH RESULTS](#)



# The FDA Purple Book: Advanced Search

Visit: <https://purplebooksearch.fda.gov>

## Purple Book

### Database of Licensed Biological Products

**Purple Book Homepage**

- [About Purple Book](#)
- [User Guide](#)
- [FAQs](#)
- [Patent List](#)
- [Download Purple Book Data](#)

### Advanced Search

Enter data into the search box to search all products in the Purple Book. Click 'Additional Search Filters' to expand your search by entering additional terms or selecting from the drop-down list. The Advanced Search table below will update in real time and display all products that match any of the terms entered.

1

☰
⌵
📄
🔗
✖

Showing 1 to 12 of 12 rows 50 rows per page

Product Label	Applicant	Proprietary Name	Proper Name	License Type	Strength	Dosage Form	Route of Administration	Product Presentation	Status
	Immunex Corporation	Enbrel	etanercept	351(a)	25MG	For Injection	Subcutaneous	Single-Dose Vial	Disc
	Immunex Corporation	Enbrel	etanercept	351(a)	25MG	For Injection	Subcutaneous	Multi-Dose Vial	Rx
	Immunex Corporation	Enbrel	etanercept	351(a)	50MG/ML	Injection	Subcutaneous	Pre-Filled Syringe	Rx
	Immunex Corporation	Enbrel	etanercept	351(a)	25MG/0.5ML	Injection	Subcutaneous	Pre-Filled Syringe	Rx
	Immunex Corporation	Enbrel	etanercept	351(a)	25MG/0.5ML	Injection	Subcutaneous	Single-Dose Vial	Rx
	Immunex Corporation	Enbrel	etanercept	351(a)	50MG/ML	Injection	Subcutaneous	Autoinjector	Rx
	Immunex Corporation	Enbrel Mini	etanercept	351(a)	50MG/ML	Injection	Subcutaneous	Single-Dose Cartridge	Rx
	Sandoz Inc.	Erelzi	etanercept-szszs	351(k) Biosimilar	25MG/0.5ML	Injection	Subcutaneous	Pre-Filled Syringe	Rx
	Sandoz Inc.	Erelzi	etanercept-szszs	351(k) Biosimilar	50MG/ML	Injection	Subcutaneous	Pre-Filled Syringe	Rx





# The FDA Purple Book: Interchangeable Products

Visit: <https://purplebooksearch.fda.gov>


**Biosimilar(s)** ⓘ

No biosimilar data at this time.

**Interchangeable(s)** ⓘ

**Proprietary Name**  
*Rezvoglar*


**Proper Name**  
*insulin glargine-aglr*



PRODUCT LABEL

**Proprietary Name**  
*Semglee*

**Proper Name**  
*insulin glargine-yfgn*






PRODUCT LABEL

**Reference Product(s)** ⓘ

**Proprietary Name**  
*Lantus*



**Proper Name**  
*insulin glargine*

PRODUCT LABEL

**Proprietary Name**  
*Semglee*


**Proper Name**  
*insulin glargine*

PRODUCT LABEL

**Proprietary Name**  
*Toujeo*


**Proper Name**  
*insulin glargine*



PRODUCT LABEL

**Proprietary Name**  
*Rezvoglar*

**Proper Name**  
*insulin glargine-aglr*



PRODUCT LABEL

**Proprietary Name**  
*Semglee*




**Proper Name**  
*insulin glargine-yfgn*




PRODUCT LABEL

**Proprietary Name**  
*Lantus*

**Proper Name**  
*insulin glargine*

PRODUCT LABEL



# The FDA Purple Book: Glossary of Terms

Visit: <https://purplebooksearch.fda.gov>

The screenshot shows the FDA Purple Book website interface. At the top, it says "An official website of the United States government" and "U.S. FOOD & DRUG ADMINISTRATION". The main heading is "Purple Book Database of Licensed Biological Products". A search bar is present with the placeholder text "Enter at least 3 letters". A sidebar on the left contains links: "Purple Book Homepage", "About Purple Book", "User Guide", "FAQs", "Patent List", and "Download Purple Book Data". A dark blue overlay on the right side is titled "Glossary" and contains a search input field with the placeholder "Search for a term..." and an example "Example: 'Biosimilar'". Below the search field, a list of terms is shown under the heading "3": "351(a)", "351(k) Biosimilar", and "351(k) Interchangeable". Under the heading "A", the terms "Applicant (sponsor)" and "Approval Date" are listed. Under the heading "B", the term "Biological Product" is listed. A "Purple Book Glossary" button is visible in the top right of the main page.

3 Glossary



# FDA Resources and Materials

[www.fda.gov/biosimilars](http://www.fda.gov/biosimilars)

# Resources for Providers

[www.fda.gov/drugs/biosimilars/overview-health-care-professionals](http://www.fda.gov/drugs/biosimilars/overview-health-care-professionals)

- >Fact Sheets >Infographics >Videos
- >Medscape Continuing Medical Education Courses

Please note: a Medscape login is required to access these activities.

- [Biosimilars 102: Interchangeability, Extrapolation, and Immunogenicity -- A Regulatory Process Primer \(medscape.org\)](#)
- [Navigating the Maze: Expert Guidance on Understanding and Integrating Biosimilars in Practice](#)
- [Biosimilars in the Real World: Perspectives for Staying Within the Scope of Care](#)
- [Biosimilars 101: A Primer for Your Practice](#)
- [Test Your Skill: Incorporating Biosimilars Into the Management of Patients With Immunological Conditions](#)
- [Putting the Patient Into Perspective: Strategies for Educating Patients About Biosimilars](#)

## Multimedia Education Materials for Health Care Providers

### Fact Sheets

**Overview of Biosimilar Products**

Biosimilars are safe and effective biological medications for treating many diseases, 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**

Biosimilars are biological products, which means they are made from living organisms or their components. They are not synthetic chemicals. They are made from the same or similar building blocks as the reference product. They are made from the same or similar building blocks as the reference product. They are made from the same or similar building blocks as the reference product.

**Widespread Comparison**

Reference Product:

Approved Biosimilar:

**Biosimilar Regulatory Review and Approval**

Biological products (biologics) are the fastest-growing class of medications in the United States and account for a substantial and growing portion of health care costs. The Biological Products Comparison and Innovation Act of 2009 created an accelerated approval pathway to provide patients with greater access to safe and effective biological products. This pathway helps reduce the time and cost of development without compromising safety and effectiveness.

**Overview of the Approval Process**

- All FDA-approved biologics undergo a rigorous review process to ensure their safety, efficacy, and quality.
- A biosimilar product is approved if it is shown to be highly similar to the reference product, with no clinically meaningful differences in safety, efficacy, or quality.
- The goal of a biosimilar development program is to demonstrate biosimilarity to the reference product. This is done through a series of studies, including preclinical, pharmacokinetic, and clinical studies.

**Key Steps in the Approval Process:**

1. Preclinical studies to demonstrate similarity in safety, efficacy, and quality.
2. Submission of a Biologics License Application (BLA) to the FDA.
3. FDA review and approval of the BLA.

**Interchangeable Biological Products**

An interchangeable biological product is a biosimilar that meets additional requirements and is interchangeable with the reference product in the pharmacy, dispensing, and patient adherence. Interchangeable biological products have additional requirements for safety, efficacy, and quality. Interchangeable biological products may help increase patient access to biologics.

**Interchangeable Biosimilars**

- An interchangeable biological product is a biosimilar that meets additional requirements and is interchangeable with the reference product in the pharmacy, dispensing, and patient adherence.
- Interchangeable biological products have additional requirements for safety, efficacy, and quality.

**Pharmacy-Level Substitution**

**Interchangeable Biosimilar Approval Process**

- To be an interchangeable biosimilar, a biosimilar must demonstrate that it is highly similar to the reference product, with no clinically meaningful differences in safety, efficacy, or quality.
- The biosimilar must also demonstrate that it is interchangeable with the reference product in the pharmacy, dispensing, and patient adherence.

Sign up for a biosimilar resources for health care professionals at [www.fda.gov/biosimilars](http://www.fda.gov/biosimilars)

• [Overview of Biosimilar Products](#)

• [Biosimilar Regulatory Review and Approval](#)

• [Interchangeable Biological Products](#)

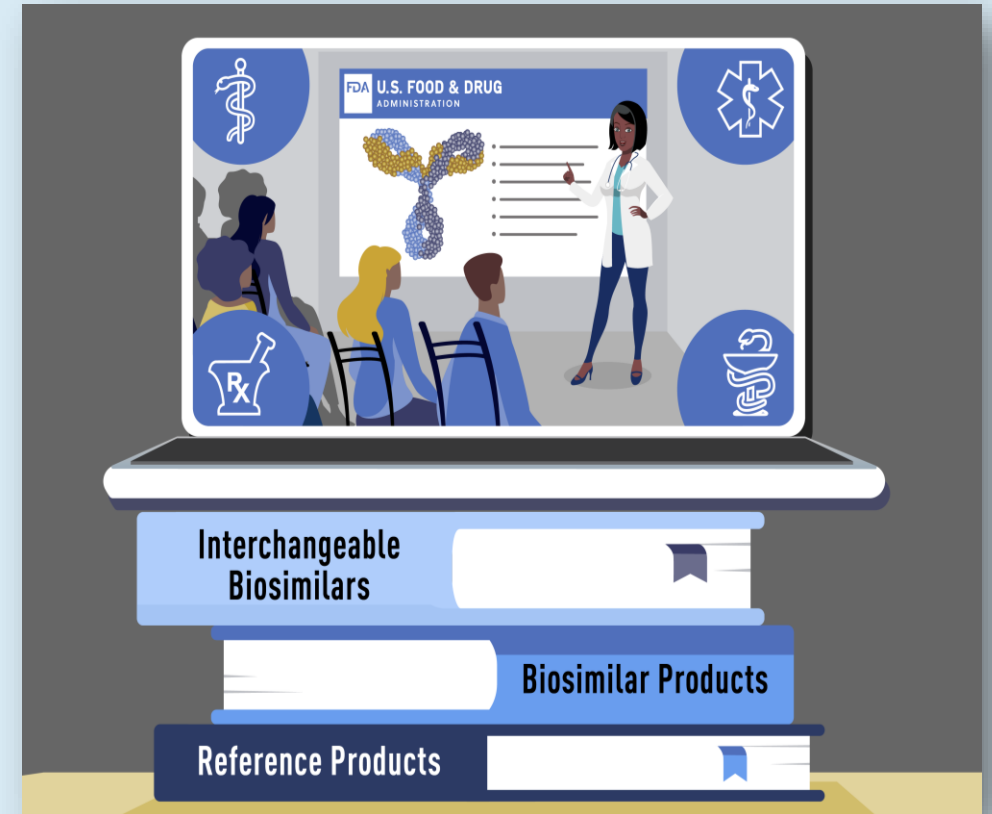
Multilingual Materials for Health Care Providers



# Resources for Providers

[www.fda.gov/drugs/biosimilars/curriculum-materials-health-care-degree-programs-biosimilars](http://www.fda.gov/drugs/biosimilars/curriculum-materials-health-care-degree-programs-biosimilars)

- Biosimilar Curriculum Toolkit contains multiple types of materials to help faculty integrate biosimilars and interchangeable products into the education and professional training of health care students.
- Goal is to increase knowledge and real-world application of concepts among students in health care degree programs (Medicine, Nursing, Physician Assoc., and Pharmacy).
- Materials are designed to meet a variety of needs and are divided into two levels of content.





# Resources for Patients

[www.fda.gov/drugs/biosimilars/basics-patients](http://www.fda.gov/drugs/biosimilars/basics-patients)

- Fact sheets, infographics, patient video

**Biosimilars:**  
What Patients Need To Know

**Biosimilars** are a type of biologic medication that is **safe and effective** for the treatment of many chronic and severe conditions, including:

- Chronic skin diseases (such as psoriasis)
- Chronic bowel diseases (such as colitis, Crohn's disease, and irritable bowel disorder)
- Diabetes
- Multiple Sclerosis
- Macular Degeneration
- Arthritis
- Kidney conditions
- Some cancers (such as breast, lung, and colon)

A biosimilar is very similar, but not identical, to an original biologic medication (also known as a reference product) that FDA has already approved. For biosimilars to be approved by FDA, studies must show that there are no differences in the safety and effectiveness of biosimilars and the original biologics.

Both a biosimilar and its original biologic:

- Are made from the same types of sources (e.g., living sources)
- Provide the same benefits when treating diseases or medical conditions
- Are given at the same strength and dosage
- Are not expected to cause new or worsening side effects

FDA has approved many biosimilars and expects to approve more in the future. For more information about individual biosimilars and the conditions they treat, please visit <https://purplebooksearch.fda.gov>

For more information on biosimilars, visit [www.FDA.gov/biosimilars](http://www.FDA.gov/biosimilars) and talk to your doctor to learn more.

**¿QUÉ ES UN BIOSIMILAR?**

- Un biosimilar es un producto biológico**

Los biosimilares aprobados por la FDA han sido comparados con un producto biológico aprobado por la FDA, al que se le conoce como un producto de referencia. Los productos de referencia y los biosimilares son:

  - Moléculas grandes, generalmente complejas
  - Productos de organismos vivos
  - Cuidadosamente monitoreados para asegurar una calidad uniforme
- Un biosimilar es muy similar a un producto de referencia**

Para su aprobación, fueron comparadas las estructuras y las funciones de un biosimilar aprobado con un producto de referencia, examinando características clave tales como:

  - Pureza
  - Estructura molecular
  - Bioactividad

Los datos de estas comparaciones deben demostrar que el biosimilar es muy similar al producto de referencia.
- Un biosimilar no tiene diferencias clínicamente significativas con un producto de referencia**

Los estudios se realizaron para demostrar que los biosimilares no tienen diferencias clínicamente significativas en cuanto a seguridad, pureza o potencia (seguridad y eficacia) en comparación con el producto de referencia:

  - Estudios farmacocinéticos, y de ser necesarios, estudios farmacodinámicos
  - Evaluación de la inmunogenicidad
  - Estudios clínicos adicionales de ser necesarios

Los estudios se pueden realizar en forma independiente o combinada.
- Un biosimilar es aprobado por la FDA después de una evaluación y pruebas exhaustivas por parte del solicitante**

Los prescriptores y pacientes no deben tener inquietudes acerca del uso de estos medicamentos en lugar de los productos de referencia porque los biosimilares:

  - Cumplen con los rigurosos estándares de aprobación de la FDA.
  - Se fabrican en instalaciones aprobadas por la FDA.
  - Se les hacen seguimientos de vigilancia posterior a la comercialización para garantizar una seguridad continuada.

Visite [www.FDA.gov](http://www.FDA.gov) para conocer más acerca de los biosimilares.

**Biosimilar and Original Biologic**

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

Biosimilars are FDA-approved biologic medications that are compared to another medication – the original biologic.

**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	Generics
Generally made from living sources	Generally made from chemicals
Require a specialized process to produce	Have a simpler process to copy
Very similar, but not identical, to original biologics	Copy of brand-name drugs
Usually less expensive than original biologics	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



# Increased Accessibility for Patients and Providers

<https://www.fda.gov/drugs/biosimilars/multimedia-education-materials-biosimilars>

• Fact sheets, infographics, and flyers in nine different languages:

- Arabic
- French
- Haitian Creole
- Korean
- Spanish
- Simplified Chinese
- Tagalog
- Traditional Chinese
- Vietnamese

**Thuốc tương tự sinh học:**  
Những điều Bệnh nhân Cần Biết

Thuốc tương tự sinh học là loại thuốc sinh học an toàn và hiệu quả để điều trị nhiều tình trạng bệnh mạn tính và nghiêm trọng, bao gồm:

- Các bệnh ngoài da mạn tính (chẳng hạn như bệnh vẩy nến)
- Bệnh đường ruột mạn tính (chẳng hạn như viêm đại tràng, bệnh Crohn và rối loạn ruột kích thích)
- Bệnh tiểu đường
- Bệnh Đa xơ cứng
- Thoái hóa Đỉnh vàng
- Viêm khớp
- Bệnh thận
- Một số bệnh ung thư (chẳng hạn như vú, phổi và đại tràng)

Thuốc tương tự sinh học rất giống, nhưng không giống hệt, với thuốc sinh học gốc (còn được gọi là chế phẩm tham chiếu) mà Cục quản lý Thực phẩm và Dược phẩm (FDA) đã phê duyệt. Để các thuốc tương tự sinh học được FDA phê duyệt, các nghiên cứu phải chỉ ra rằng không có sự khác biệt về tính an toàn và hiệu quả của thuốc tương tự sinh học và thuốc sinh học gốc.

Cả thuốc tương tự sinh học và thuốc sinh học gốc của chúng đều:

- Được tạo ra từ cùng loại nguồn (ví dụ: nguồn sống)
- Cung cấp các lợi ích tương tự khi điều trị bệnh hoặc bệnh trạng
- Được sử dụng với cùng một nồng độ và liều lượng
- Dự kiến sẽ không gây ra tác dụng phụ mới hoặc xấu đi

FDA đã phê duyệt nhiều thuốc tương tự sinh học và hy vọng sẽ phê duyệt nhiều hơn nữa trong tương lai. Để biết thêm thông tin về các loại thuốc tương tự sinh học cụ thể và các tình trạng bệnh mà chúng điều trị, vui lòng truy cập <https://purplebooksearch.fda.gov>

Để biết thêm thông tin về các thuốc tương tự sinh học, hãy truy cập [www.FDA.gov/biosimilars](http://www.FDA.gov/biosimilars) và trao đổi với bác sĩ của bạn để tìm hiểu thêm.

**生物相似性藥品監管審查和批准**

生物製品（生物製劑）是美國增長最快的一類藥物，在醫療費用中占了相當大的比例，而且還在不斷增長。2009年的《生物製劑仿製競爭和創新法》創建了一個簡化的審批途徑，為病人提供更多選擇、更安全和有效生物製劑的機會。這一途徑有助於減少藥物開發的時間和成本，同時不影響其安全性和有效性。

**審批程序概述**

- 所有FDA批准的生物製劑都受到嚴格的控制，以便確保藥物開發者和病人能夠對仿製藥品的安全性、有效性和品質有信心。
- 生物相似性藥品是一種生物製劑，與製劑的已批准的生物藥物（稱為參照藥）高度相似，並且具有與參照藥相同的結構。
- 參照藥的複雜性，必須通過獨立性試驗來證明其安全性和有效性的所有資料和資訊。
- 生物相似性藥品開發的主要目標是證明所申請生物相似性藥品與參照藥之間的生物相似性，而不是獨立證明參照藥生物相似性藥品的安全性和有效性。這通常意味著生物相似性藥品在生產前不需要進行那麼多昂貴和漫長的臨床試驗。
- 簡化途徑有助於對生物相似性藥品進行更深入的結構和組成比較。
- 因為生物製劑通常是在細胞中製成的，那就有獨特的變異性，但在仿製生物製劑的生產過程中都會產生獨特的變化（變異、糖基化）。
- FDA會在申請參考藥和仿製劑的製造過程，對從生產到交付不同階段之間的變化進行化學和生物學分析，從而確保安全性和有效性不發生變化。
- FDA在批准任何藥物後都會對其安全性和有效性，這包括觀察生產設施和參照藥生產商、製藥商提供者和病人可以提交的安全性報告。

參照藥 生物相似性藥品的製造過程

關於仿製生物相似性藥品和參照藥進行廣泛的結構和組成比較。

參照藥生物製劑在生產過程中製成，在生物製劑的生產過程中，FDA會對仿製藥品的製造過程進行廣泛的觀察。

FDA在批准任何藥物後都會對其安全性和有效性。

**Conceptos básicos sobre los biosimilares**

Los biosimilares son un tipo de medicamento biológico **seguro y eficaz** para el tratamiento de muchas enfermedades, tales como las enfermedades cutáneas e intestinales crónicas, la artritis, la diabetes, las afecciones renales, la degeneración macular y algunos cánceres.

La mayoría de los **medicamentos biológicos** tienen pequeñas diferencias entre los lotes porque generalmente están elaborados de fuentes vivas [tales como células animales, bacterias o levaduras]. Los productos biológicos se **elaboran haciendo uso de los avances de la ciencia** y por lo general, se administran por inyección.

Los biosimilares son medicamentos **aprobados por la FDA** que son muy similares, pero no idénticos, a otro medicamento al producto biológico original ya aprobado por la FDA.

Producto biosimilar y su biológico están elaborados del mismo fuente y **tienen los mismos beneficios de tratamiento**.

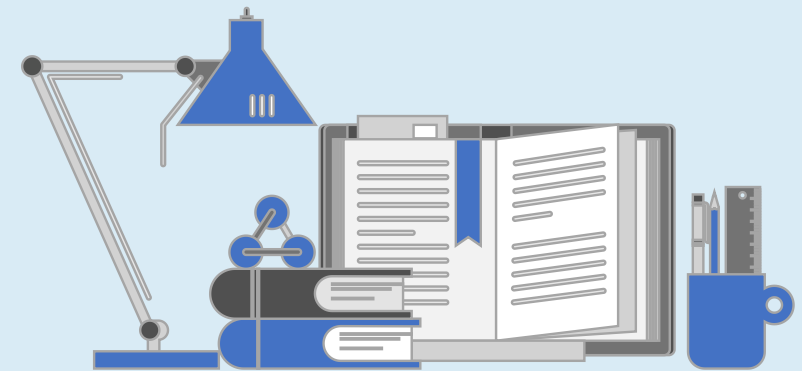
- ✓ Los mismos beneficios
- ✓ Las mismas posibles afecciones secundarias
- ✓ La misma concentración y dosis
- ✓ Se administran de la misma manera





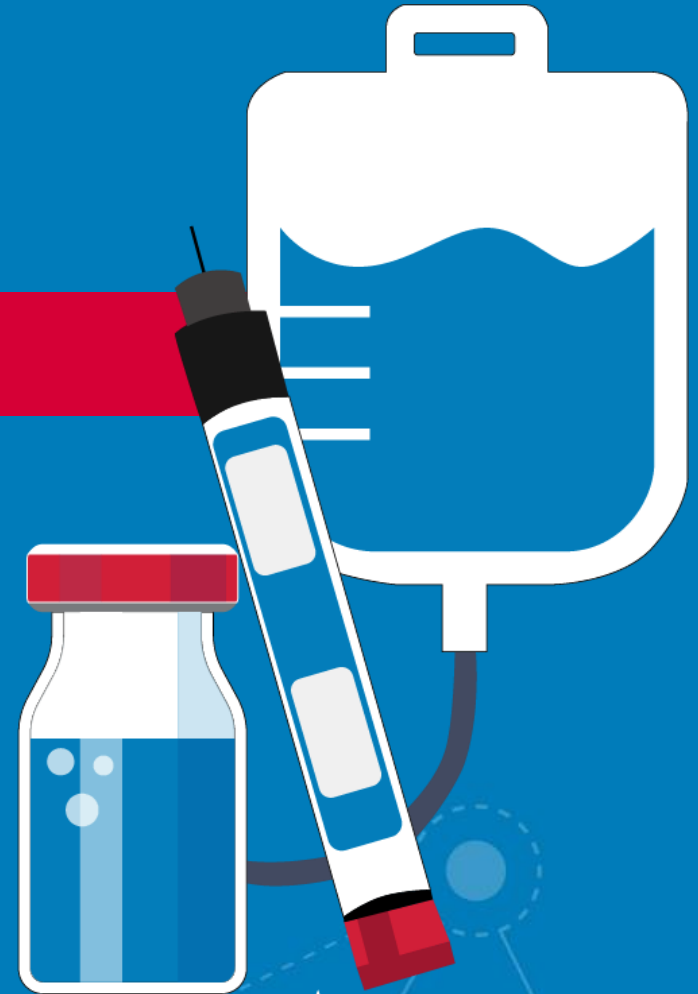
# Additional Resources

- [www.fda.gov/biosimilars](http://www.fda.gov/biosimilars) for access to all the education materials and information about biosimilar and interchangeable products.
- <https://purplebooksearch.fda.gov/> **The Purple Book: Database of Licensed Biological Products** for information on biological products, including if products are biosimilar to a reference product.
- [www.fda.gov/drugsatfda](http://www.fda.gov/drugsatfda) (**Drugs@FDA**) for information on all FDA approved drug products, including labeling and review information.
- <https://www.fda.gov/drugs/biosimilars/curriculum-materials-health-care-degree-programs-biosimilars> for curriculum materials for health care degree programs
- [Guidance Webpage](#) for guidance related to BsUFA, including details on BPCI (search on “biosimilar”)
- [CDERLearn Training and Education](#) for FDA CE, Medscape CE, and other education content- select "biosimilars" under topics.



# Thank you!

Visit [www.fda.gov/biosimilars](http://www.fda.gov/biosimilars) to learn more!



# Script Your Future Information

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