Script Your Future Biosimilars Webinar

April 2, 2024

SCRIPT YOUR FUTURE

A Campaign of the National Consumers League

Speakers

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SCRIPT YOUR FUTURE

U.S. FOOD & DRUG ADMINISTRATION

Biosimilars

What You Need to Know

National Consumers League
Pharmacy Student Education
April 2024

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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

B Biosimilar

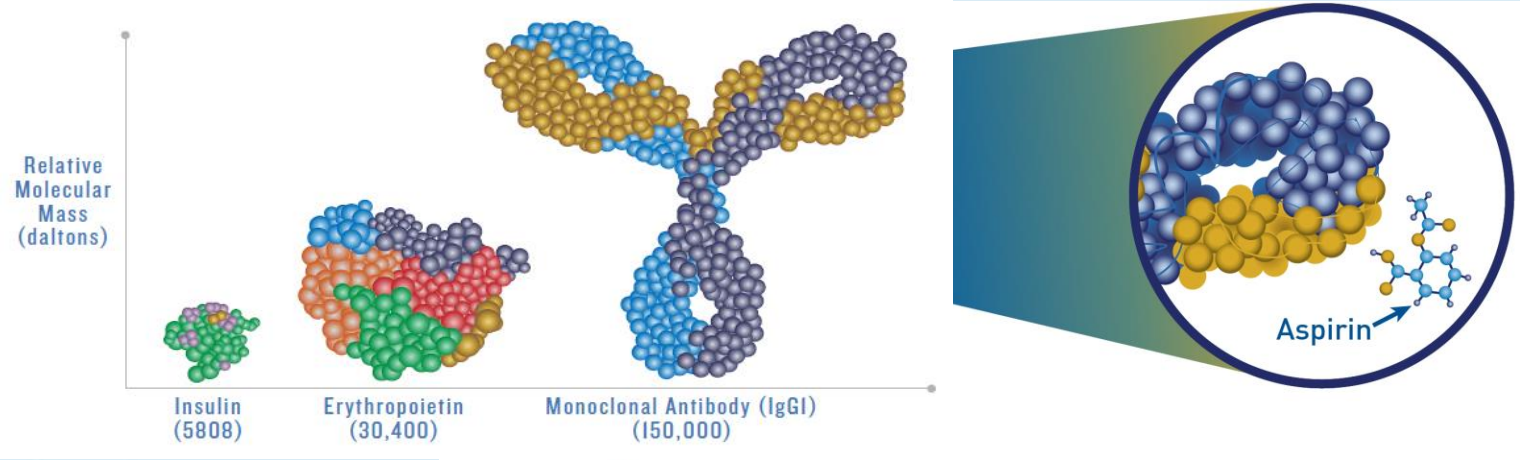
I Interchangeable Biosimilar

- **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

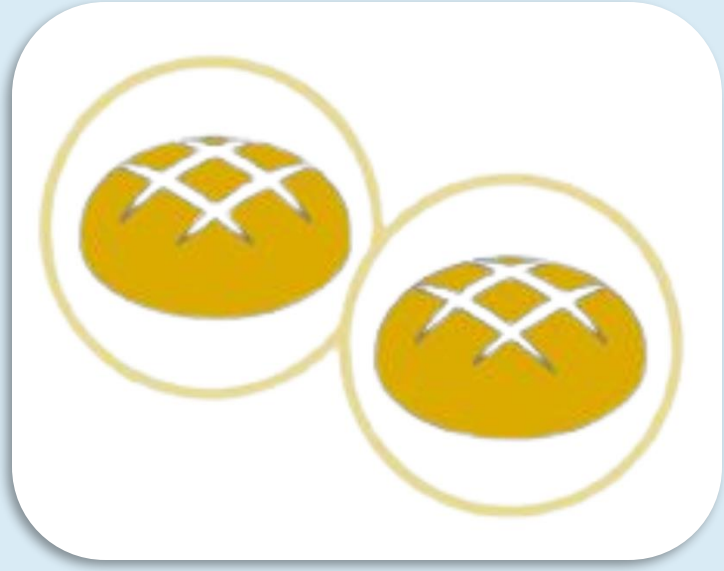
Immunogenicity assessment

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?

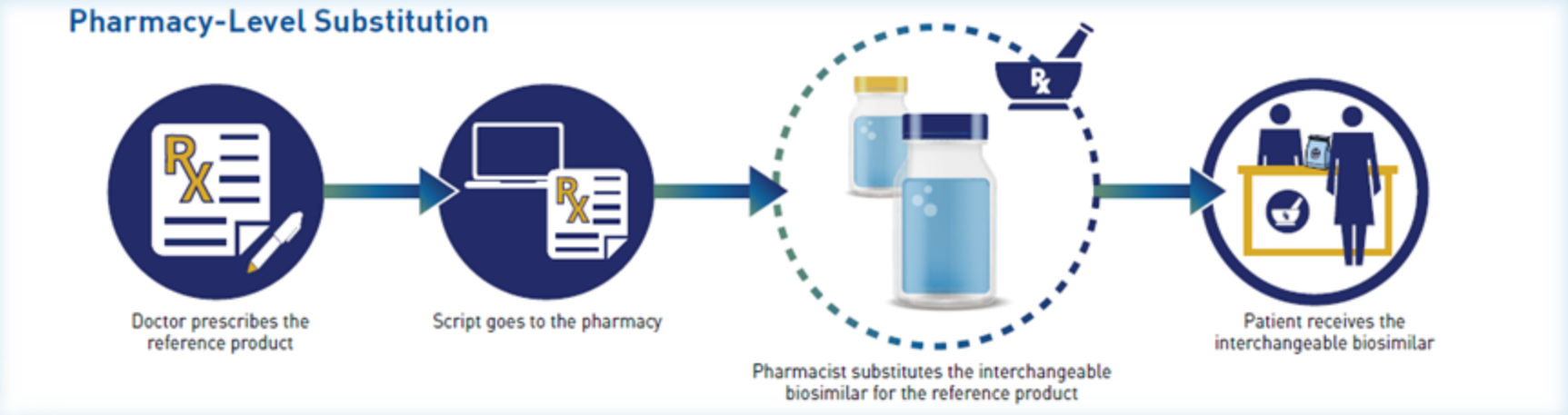
- Biosimilars and generics are both versions of medications already approved by FDA.
- Biosimilars may allow multiple companies to enter the market, which may lower the cost of a particular biologic medication.
- Biosimilars may offer more affordable treatment options to more patients.

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

Biosimilars	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
Faster development process using public information from original biologic approval	Faster development process using public information from brand-name drug approval
Usually less expensive than original biologics	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)

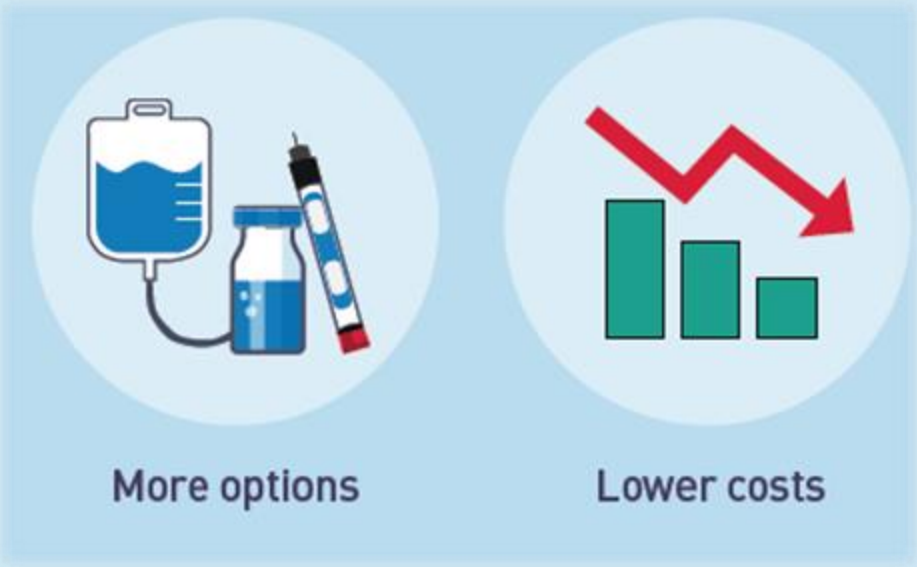
Why Would a Patient Switch to a Biosimilar?

- 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.



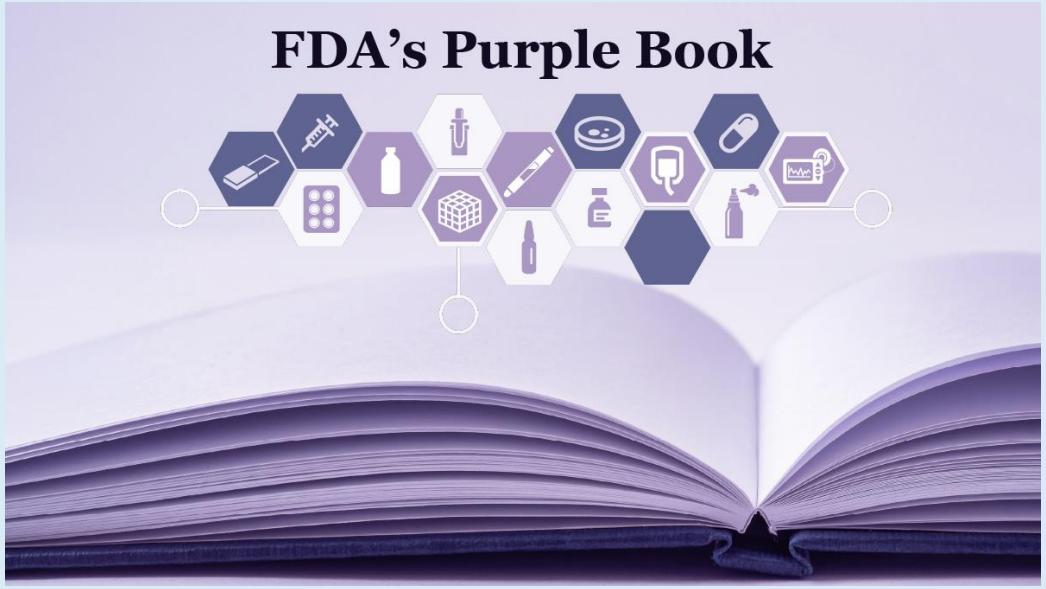
FDA's Purple Book: Database of Licensed Biological Products

www.PurpleBookSearch.fda.gov

The FDA Purple Book

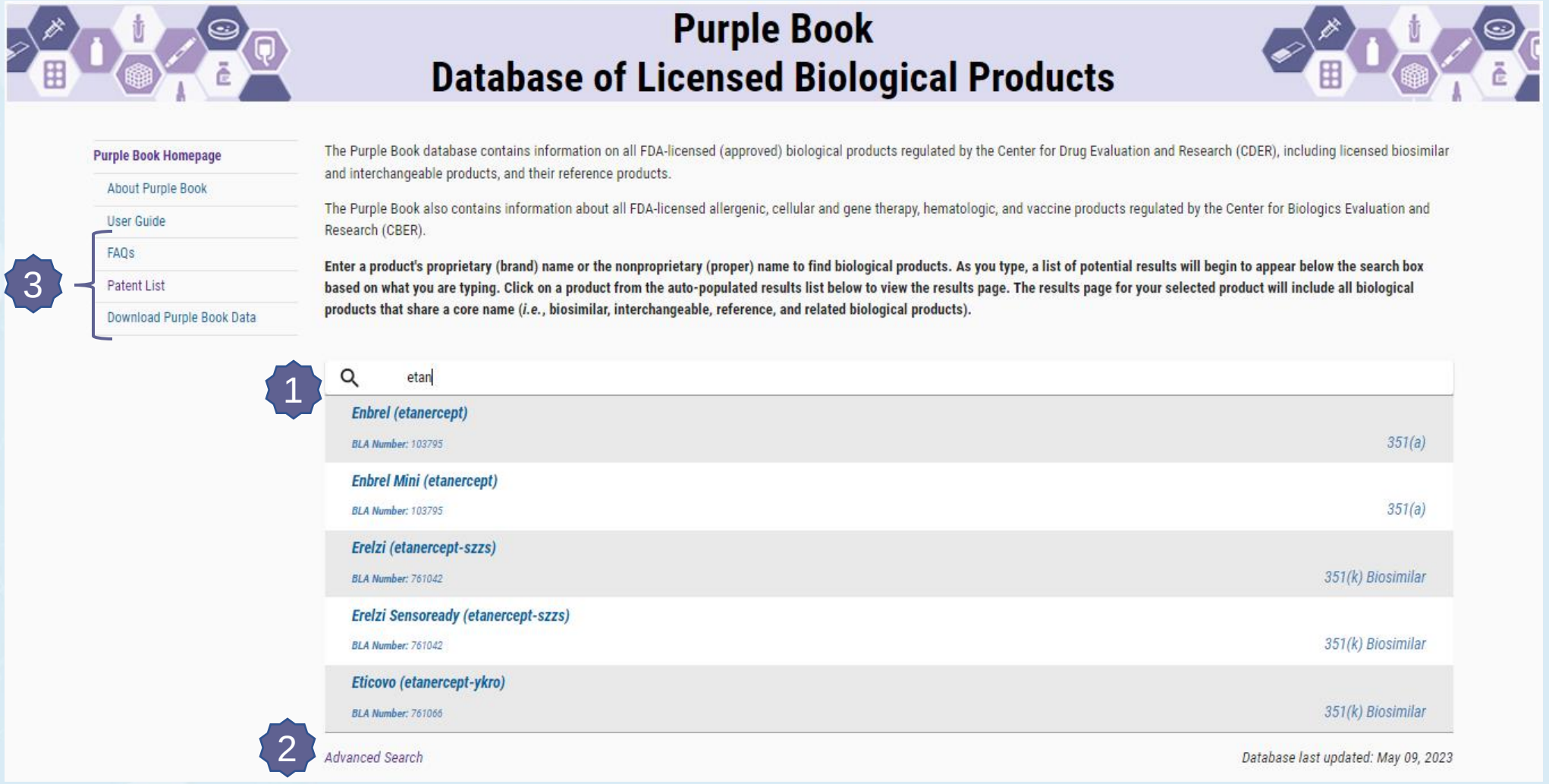
Visit: https://purplebooksearch.fda.gov

- 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



The FDA Purple Book: Simple Search Results

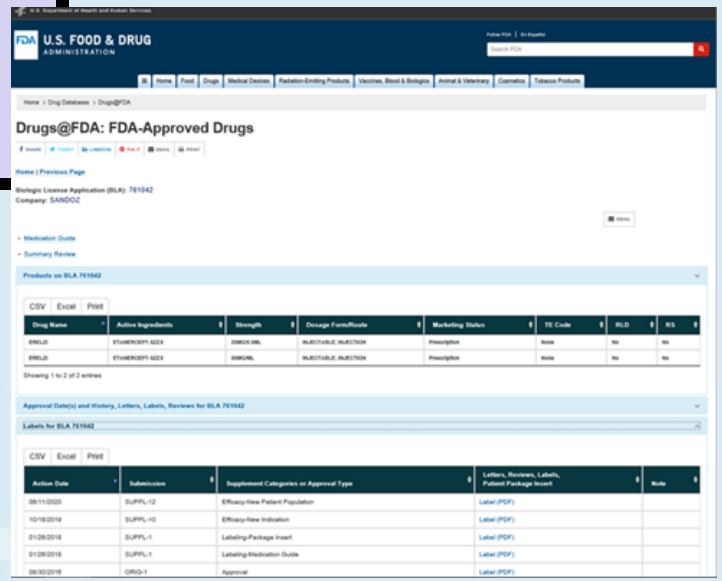
Visit: https://purplebooksearch.fda.gov

Proprietary Name
Erelzi
Erelzi Sensoready

Proper Name
etanercept-szzs

1

2 PRODUCT LABEL



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-szzs

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

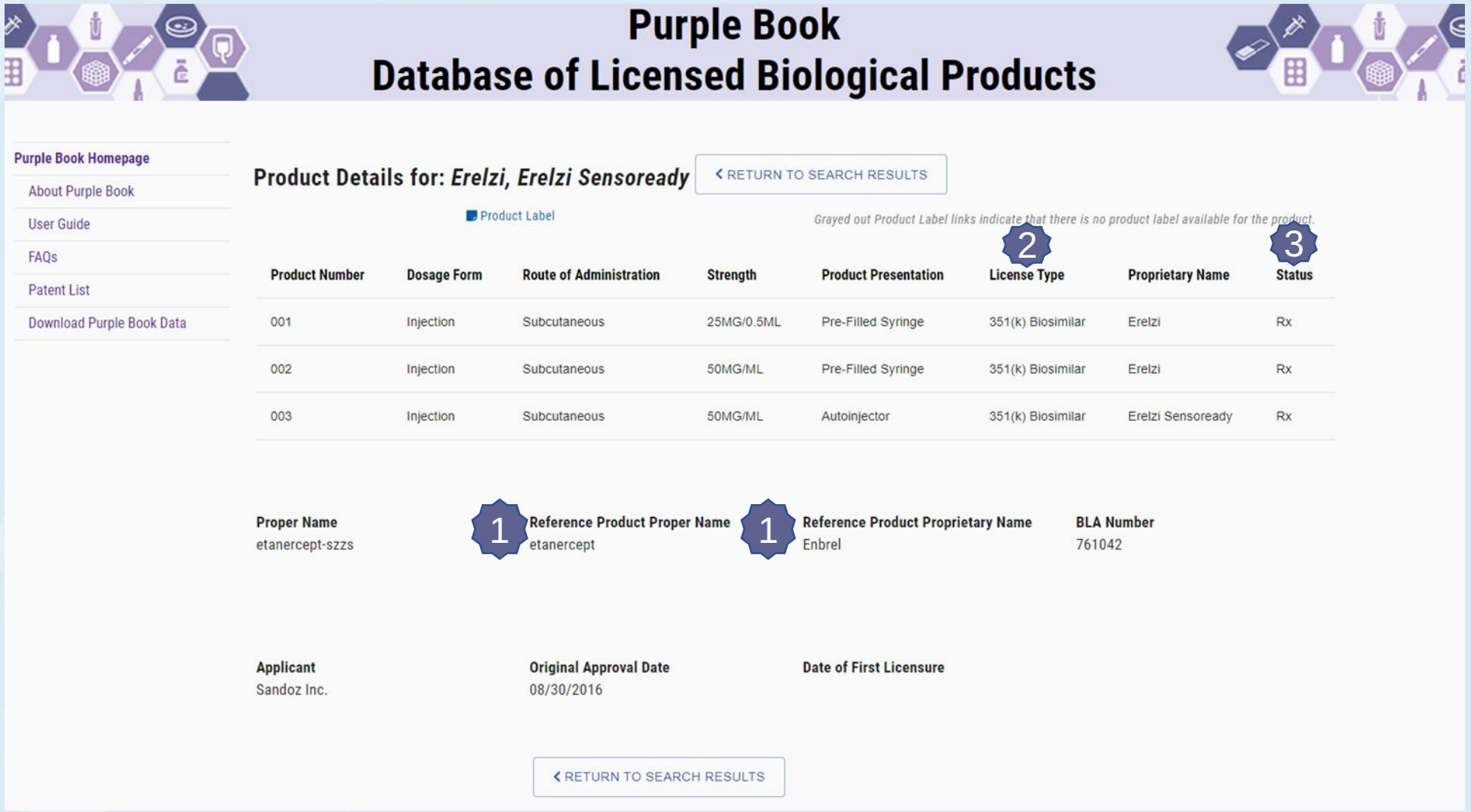
PRODUCT LABEL

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

Product Details for: *Erelzi, Erelzi Sensoready* RETURN TO SEARCH RESULTS

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 (2)	Proprietary Name	Status (3)
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.

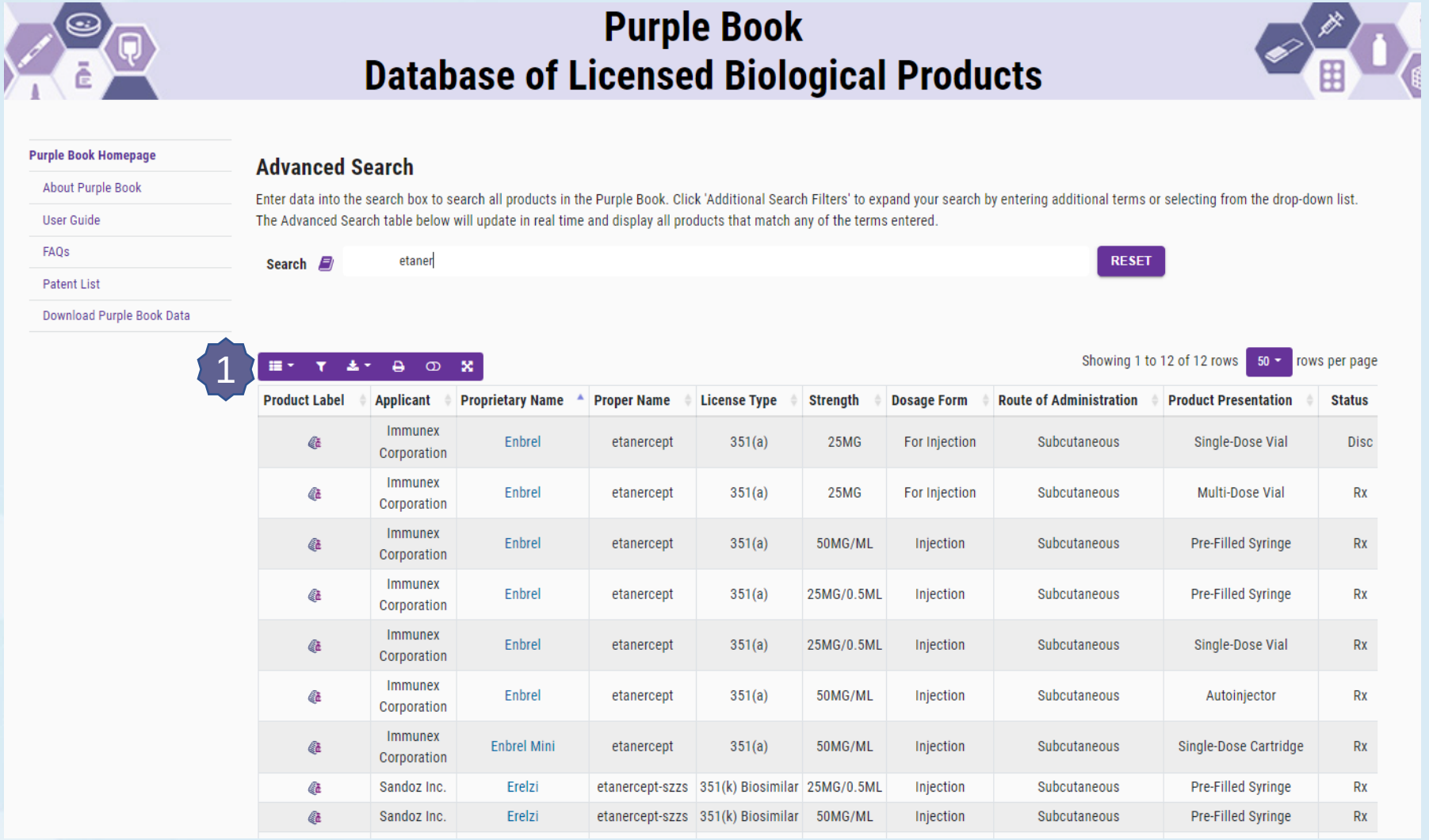
Original Approval Date
08/30/2016

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

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- Patent List
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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.

Search: etaner | RESET

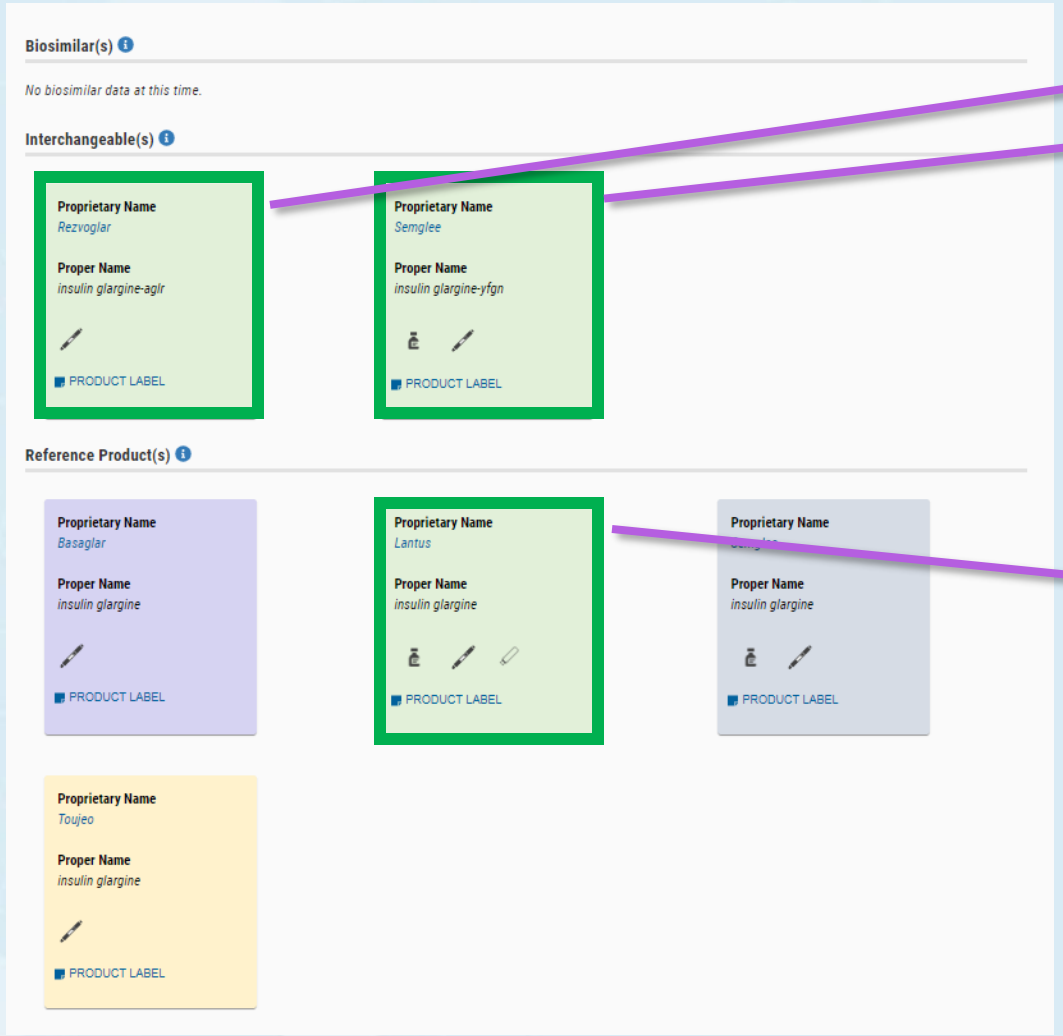
1

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-szzs	351(k) Biosimilar	25MG/0.5ML	Injection	Subcutaneous	Pre-Filled Syringe	Rx
	Sandoz Inc.	Erelzi	etanercept-szzs	351(k) Biosimilar	50MG/ML	Injection	Subcutaneous	Pre-Filled Syringe	Rx

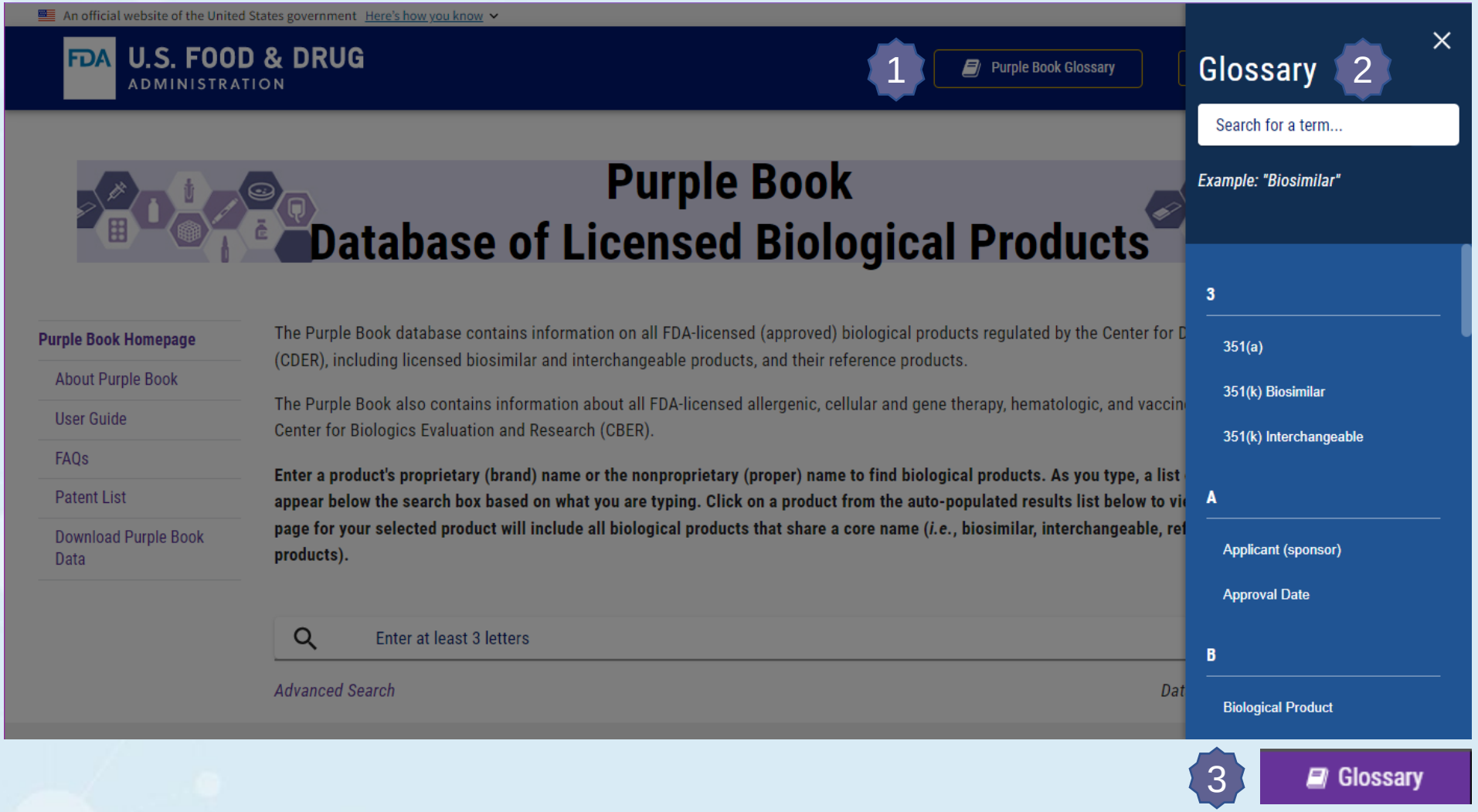
The FDA Purple Book: Interchangeable Products

Visit: https://purplebooksearch.fda.gov



The FDA Purple Book: Glossary of Terms

Visit: https://purplebooksearch.fda.gov



FDA Resources and Materials

www.fda.gov/biosimilars

Resources for Providers

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

- Biosimilar Regulatory Review and Approval

- Interchangeable Biological Products

Multilingual Materials for Health Care Providers

Resources for Providers

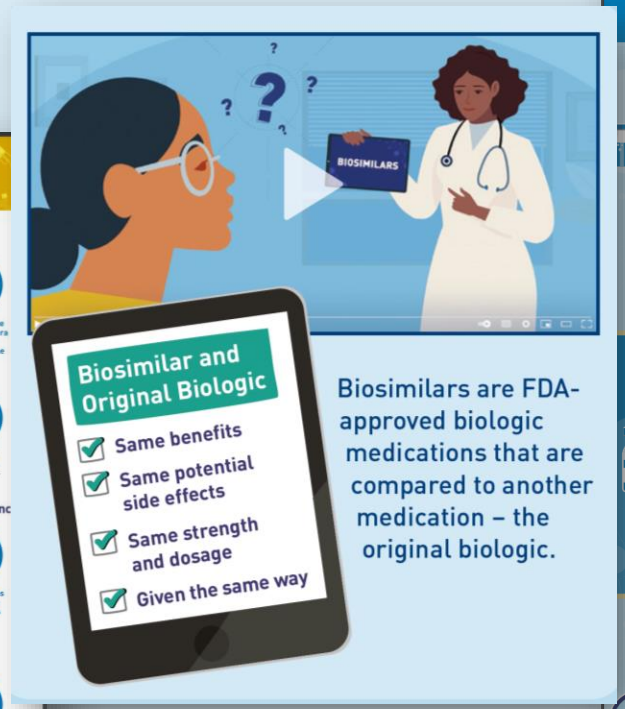
www.fda.gov/drugs/biosimilars/curriculum-materials-health-care-degree-programs-biosimilars

- 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

- Fact sheets, infographics, patient video



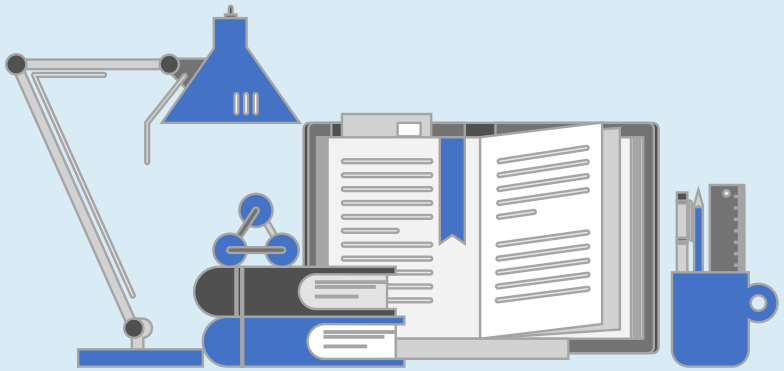
Increased Accessibility for Patients and Providers

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

Additional Resources

- 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 (**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.



U.S. FOOD & DRUG ADMINISTRATION

Thank you!

Visit www.fda.gov/biosimilars to learn more!

Script Your Future Information

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https://scriptyourfuture.org/