



FDA Drug Topics: **Biosimilars: A Review of Scientific, Regulatory, and Clinical Considerations for Health Care Providers**

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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
	Trastuzumab	B B B B B
Autoimmune	Infliximab	B B B B
	Etanercept	B B
	Adalimumab	B I B B B B B B B
	Insulin Glargine	I I
Ophthalmology	Ranibizumab	B I

Biosimilar
 Interchangeable Biosimilar

- **41 Biosimilars Approved**
- **29 Currently marketed**

*as of May 31, 2023

Learning Objectives

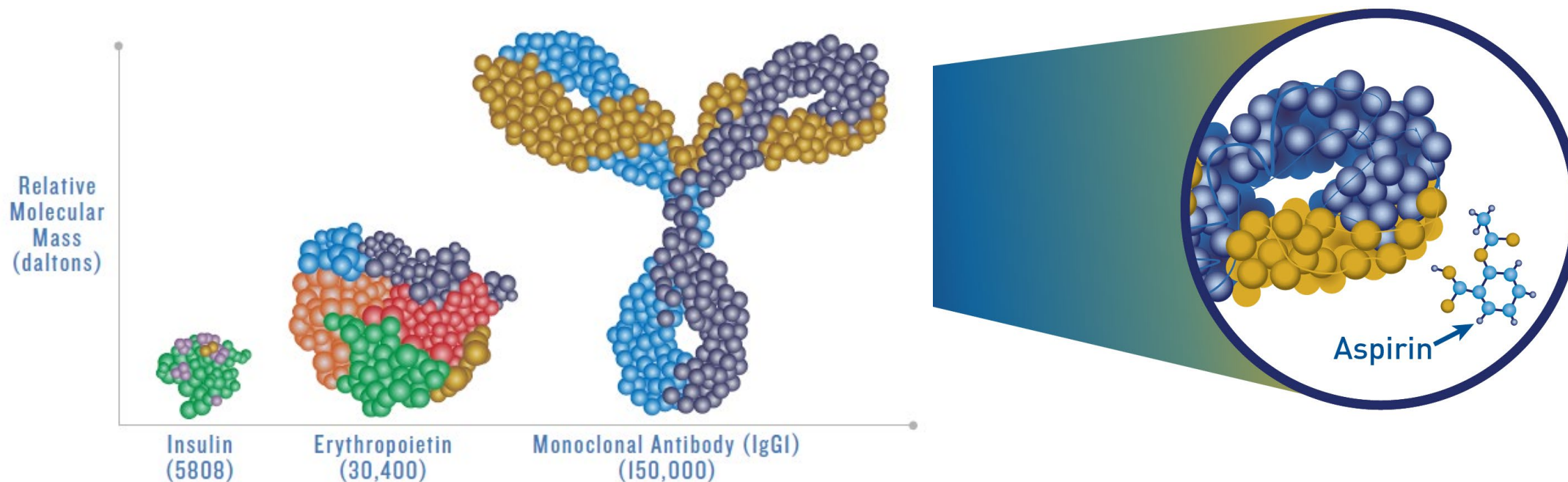


1. Review the key definitions, nomenclature, labeling, issues of interchangeability, and similarities and differences between biosimilars and reference biologics.
2. Describe how biologics differ from small molecules (size, complexity, inherent variation) and compare the biosimilar and generic approval pathways.
3. Explain the statutory requirements and approval process for biosimilars and interchangeables.
4. Discuss considerations for prescribing and dispensing biosimilars and interchangeable biosimilars.
5. Summarize the new resources available for health care providers and faculty to learn more about biosimilar and interchangeable products and how to use the Purple Book Database of Licensed Biological Products.

Biosimilar and Interchangeable Products: Scientific Concepts and Regulatory Framework

Biological Products

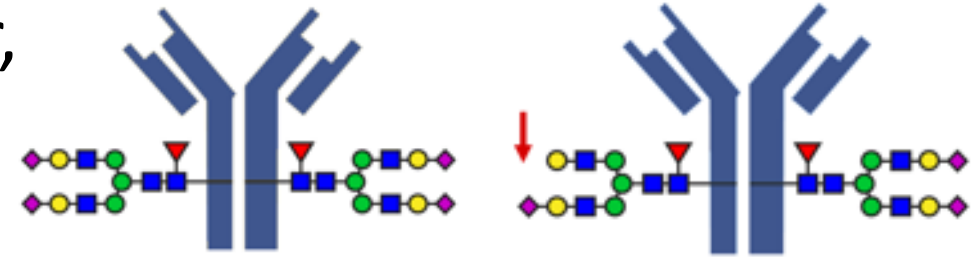
- Biologics are generally large and produced from living systems
- They range in size and complexity
- Examples: therapeutic proteins (hormones, growth factors, monoclonal antibodies), vaccines, blood products



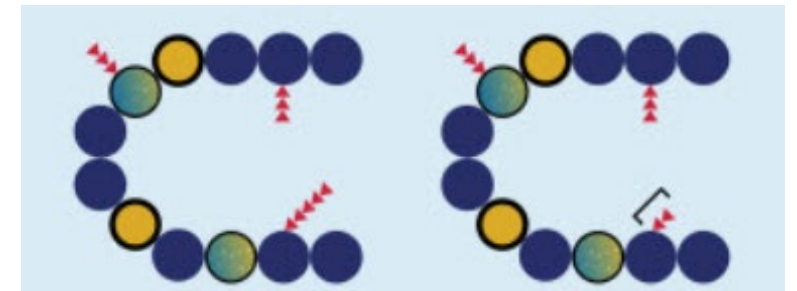
Therapeutic Proteins: Complexity



- Cells can make exact copies of a protein but other add-ons and changes may occur, resulting in different versions of the molecule (inherent variation)



- Millions of slightly different versions of the same protein or antibody per dose or batch



- Biologics manufacturers try to keep a consistent mix of variants across batches of their products and over time

Biological Product Regulation

- **351(a) “stand alone” Biologics License Application (BLA):** contains all information and data necessary to demonstrate that the proposed biological product is safe, pure and potent
- **The Biologics Price Competition and Innovation Act of 2009 (BPCI Act)**
 - Created an **abbreviated licensure pathway (351(k))** for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product (originator biological product)

Key Definitions from the BPCI Act



Reference Product

A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar product is compared



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 Product

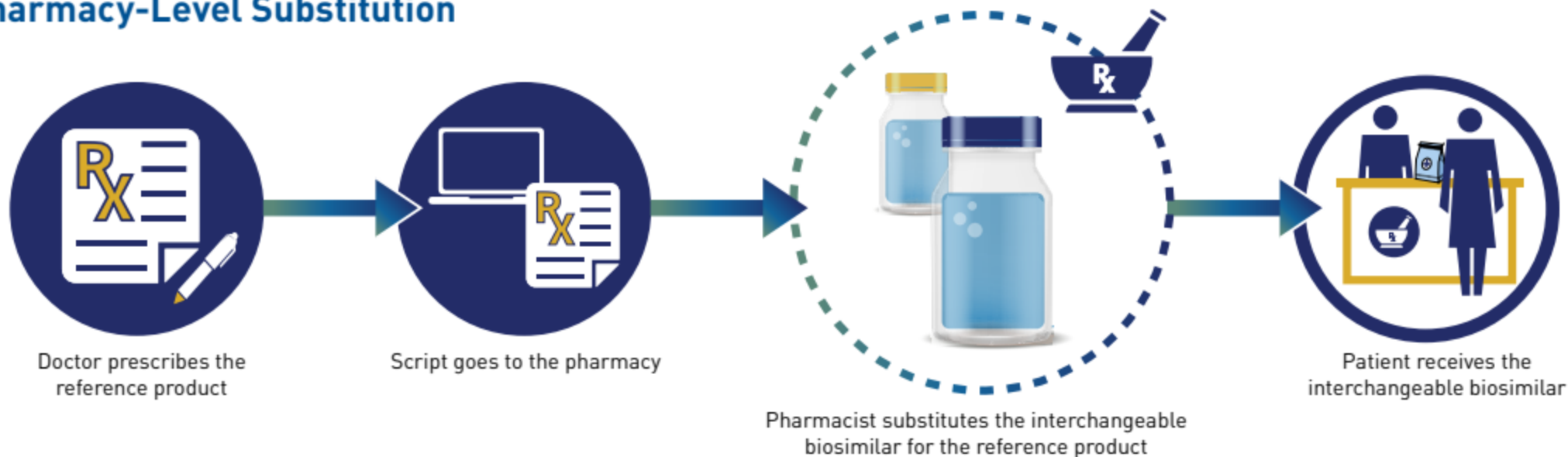
- Is a biosimilar
- Expected to produce the same clinical result as the reference product (RP) in any given patient
- Switching between the proposed product and the RP does not ↑safety risks or ↓effectiveness compared to using the RP without switching

Why Seek Interchangeability?

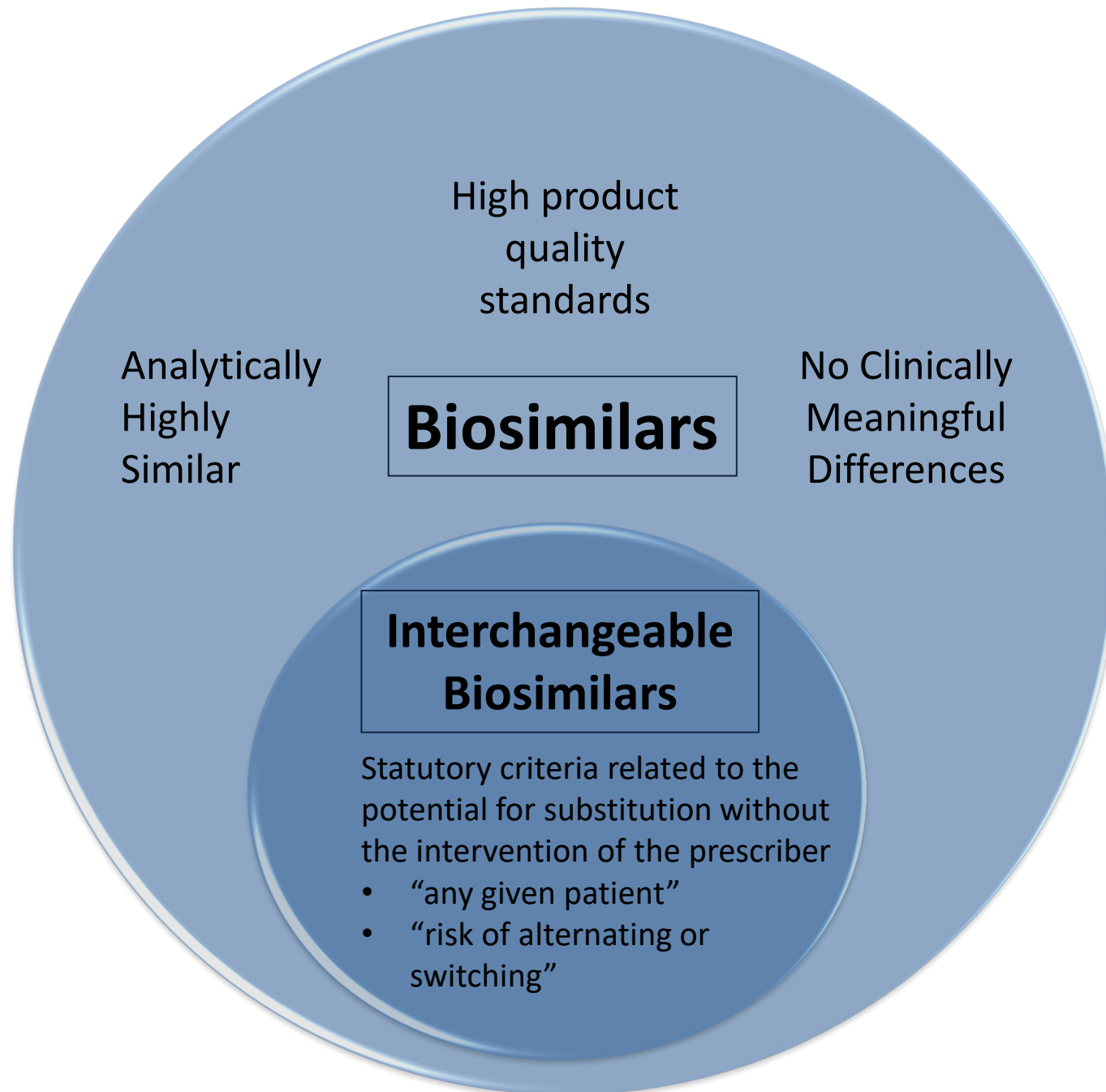


An interchangeable biosimilar product can be **substituted for the reference product at pharmacies** without the intervention of the prescribing health care provider, subject to state pharmacy laws.

Pharmacy-Level Substitution



Biosimilars and Interchangeable Biosimilars



- Applicants request licensure as a biosimilar or interchangeable biosimilar
- An applicant may be first approved as a biosimilar but later seek interchangeability
- The analytical similarity and product quality standards are **the same** for biosimilars and interchangeable biosimilars
- Statutory criteria related to the potential for substitution without the intervention of the prescriber

General Requirements



A 351(k) application must include information demonstrating that the biological product:

- Is **biosimilar** to a reference product
 - **Highly similar to and has no clinically meaningful differences from the FDA-approved reference product**
- Utilizes the **same mechanism(s) of action** for the proposed condition(s) of use -- but only to the extent the mechanism(s) are known for the reference product;
- **Condition(s) of use** proposed in labeling **have been previously approved** for the reference product;
- Has the **same route of administration, dosage form, and strength** as the reference product; and
- Is manufactured, processed, packed, or held in a facility that **meets standards** designed to assure that the biological product continues to be **safe, pure, and potent.**

Different Goals for “Stand-alone” vs. Biosimilar Development

“Stand-alone”: 351(a) BLA

Goal: To establish *de novo* safety and efficacy of a new product



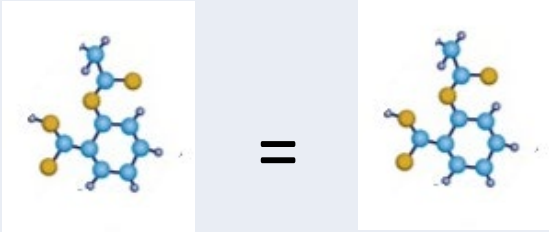
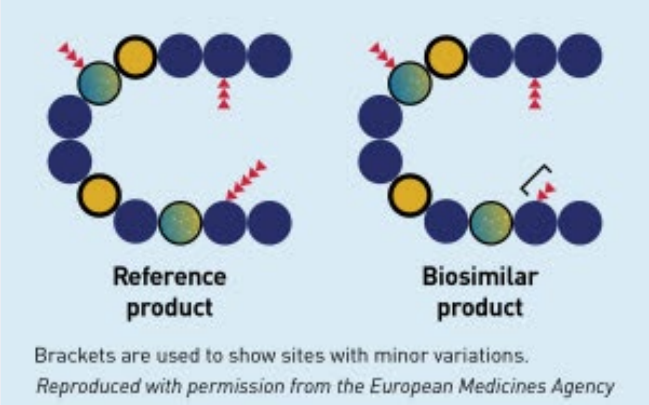
“Abbreviated”: 351(k) BLA

Goal: To demonstrate biosimilarity (or interchangeability) to a reference product based on comparative assessments



Generic vs. Biosimilar



	Generic (Orange Book)	Biosimilar (Purple Book)
Assessment	“Same” Active Ingredient PK Bioequivalence	“Highly Similar” No Clinically Meaningful Differences
Example schematic of product comparisons. Comparative Analytical data expected for both products	 <p>Reference Listed Drug Generic Drug</p>	 <p>Reference product Biosimilar product</p> <p><small>Brackets are used to show sites with minor variations. Reproduced with permission from the European Medicines Agency</small></p>
Clinical Pharmacology Studies	Compare PK, when applicable	Compare PK, and PD, when applicable
Other clinical study(ies)	-	Assess immunogenicity; may further evaluate safety and efficacy

Both are “abbreviated” development pathways that have distinct statutory requirements and scientific expectations supporting their approval.

**FDA's Recommended Approach to
the Development of Biosimilars
and Interchangeable Biosimilars**

Comparative Analytical Assessment is the Foundation



- Compare multiple physicochemical and biological attributes of each product
 - Analytical studies are generally more **sensitive** than clinical studies in detecting differences between products, should differences exist
 - A biosimilar product with **highly similar structure and function** to the reference product should behave like the reference product
- Analyze multiple lots of the reference product and proposed biosimilar for product quality attributes, including:
 - Primary amino acid sequence
 - Higher order structure (protein folding)
 - Post-translational modifications (glycosylation, etc.)
 - Heterogeneity (charge, size, aggregates, etc.)
 - Biological activity - evaluation of attributes that affect the known MoAs



CAA Example 1: Semglee (insulin glargine-yfgn) vs US-Lantus: Quality Attributes Compared*



Primary structure

- Amino acid sequence and mass

Higher order structure

- Conformation
- Secondary structure
- Tertiary and higher order structures
- Hydrodynamic radius
- Disulfide bonds

Product Variants

- Deamidation
- Glycerol ester
- Citric acid conjugate
- Acetylation

Mitogenic Activity

- IR-A phosphorylation
- Mitogenic assay (Sao2 cells)
- IR-A binding kinetics
- IGF1R binding kinetics

Metabolic Activity

- IR-B phosphorylation
- Glucose uptake assay
- IR long form receptor binding kinetics
- IR autophosphorylation
- Adipogenesis assay
- Inhibition of stimulated lipolysis assay

Protein Concentration

- Activity and concentration in U/mL

Other

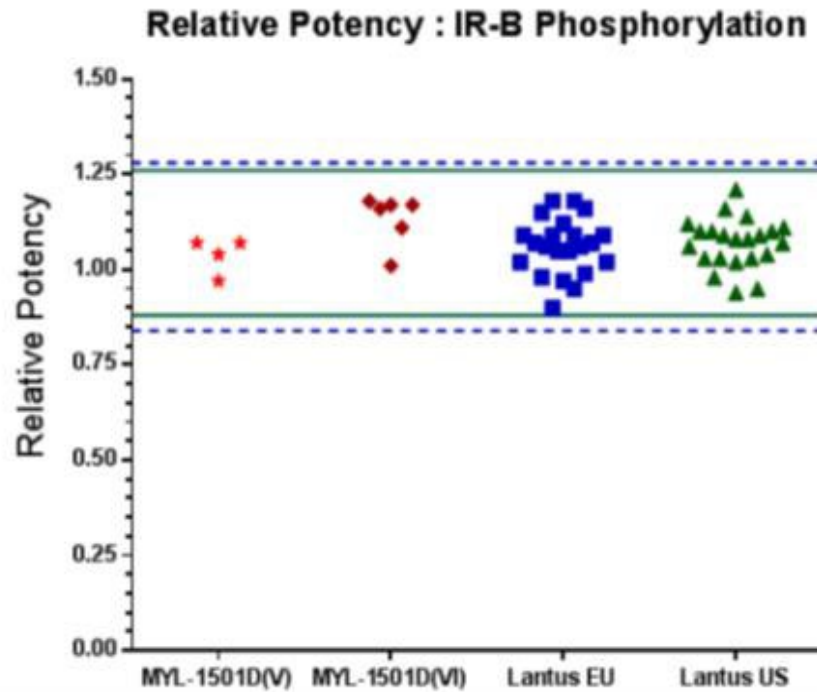
- Zinc content
- Aggregates/High molecular weight proteins
- Isoelectric point

*Not an exhaustive list; Information summarized and adapted from the [Product Quality Review](#) available on drugs@fda

CAA Example 1: Semglee (insulin glargine-yfgn) vs US-Lantus: Insulin Receptor IR-B Phosphorylation



Figure 13: Scatter Plot Distribution for Relative potency (IR-B phosphorylation activity) of MYL-1501D, EU-approved Lantus[®] and US-approved Lantus[®]



These studies provide data to support the physiochemical structural and functional similarity of MYL-1501D to US-Lantus and evaluate the impact of any differences identified.



Purity



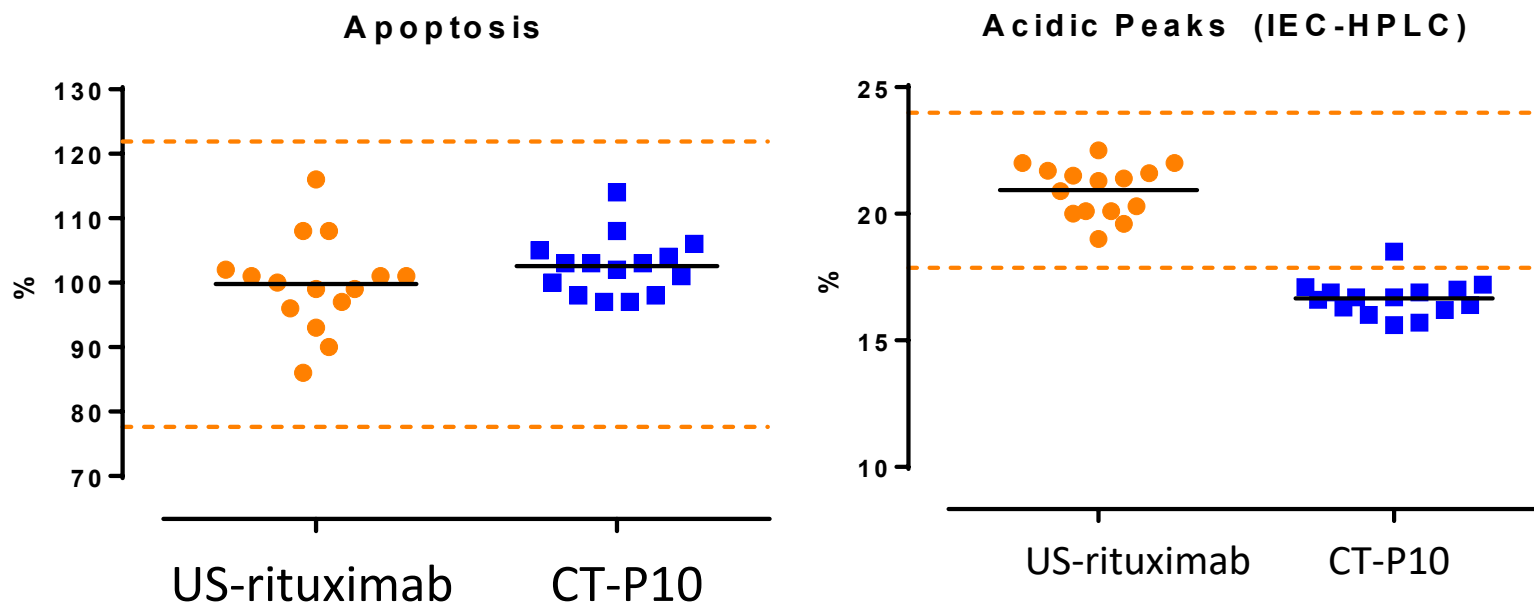
Molecular structure



Bioactivity

- Green lines represent the quality range (QR) limits (mean \pm 3SD of US-Lantus).
- The values of relative IR-B phosphorylation activity for all MYL-1501D lots are 100% within the QR of US-Lantus

CAA Example 2: CT-P10 vs US-Rituximab: Potency and Charge Variants



The black bars represent the mean percentages.
The orange lines represent the QR limits (mean \pm 3SD of the US-rituximab).

Additional Analytical Studies Showed:

- Charge peaks contain same variants
- Similar biological activity between both products for each peak



Molecular structure



Bioactivity

Role of Clinical Studies



- As a scientific matter, FDA expects an adequate clinical PK, and PD if relevant, comparison between the proposed biosimilar product and reference product and a clinical immunogenicity assessment
- Additional clinical studies are not considered “pivotal” in the way Phase 3 clinical trials are for standalone development
- Add to the totality-of-the-evidence that supports a demonstration of biosimilarity

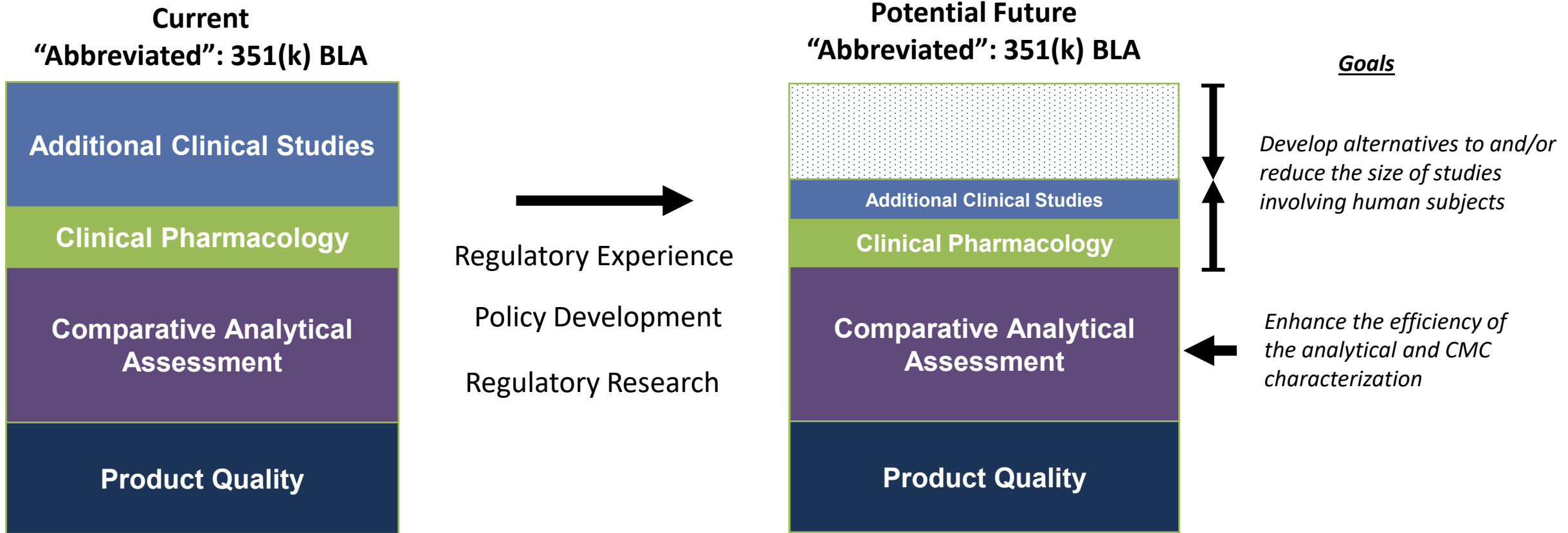


Type of Clinical Data



- Clinical Pharmacology Studies
 - **PK and/or PD** is generally considered the most sensitive *clinical study/assay* in which **to assess for differences between products**, should they exist
 - **PK and PD similarity** data supports a demonstration of biosimilarity with the assumption that similar exposure (and pharmacodynamic response, if applicable) will provide **similar efficacy and safety** (i.e., an exposure-response relationship exists)
 - Use of a **single scientifically appropriate PD biomarker or a composite of more than one** relevant PD biomarker to demonstrate PD similarity can reduce residual uncertainty.
- At least 1 clinical study that includes a comparison of the **immunogenicity** of the proposed and reference product generally will be expected
- A **comparative clinical study that compares safety and efficacy in patients** is currently expected if there are residual uncertainties about whether there are **clinically meaningful differences** between the proposed and reference products based on structural and functional characterization, human PK and PD data, and clinical immunogenicity assessment.

Focused Efforts to Streamline Biosimilar Development



Clinical Program Example 1: Semglee (insulin glargine-yfgn) vs US-Lantus PK/PD Compared



Figure 2. Mean plasma M1 concentration versus time profiles by treatment in Study MYL-1501D-1003

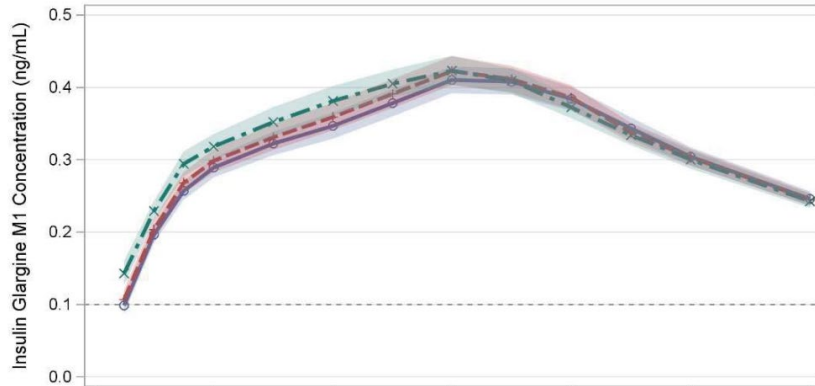
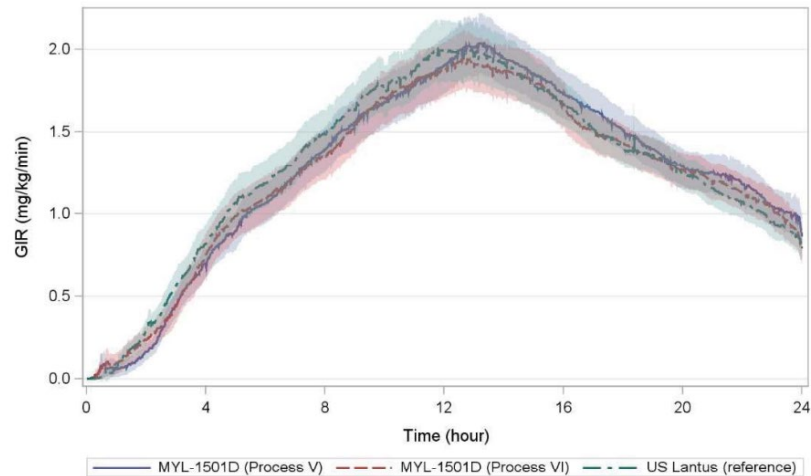


Figure 3. Mean GIR versus time profile by treatment in Study MYL-1501D-1003



PK/PD Similarity Study

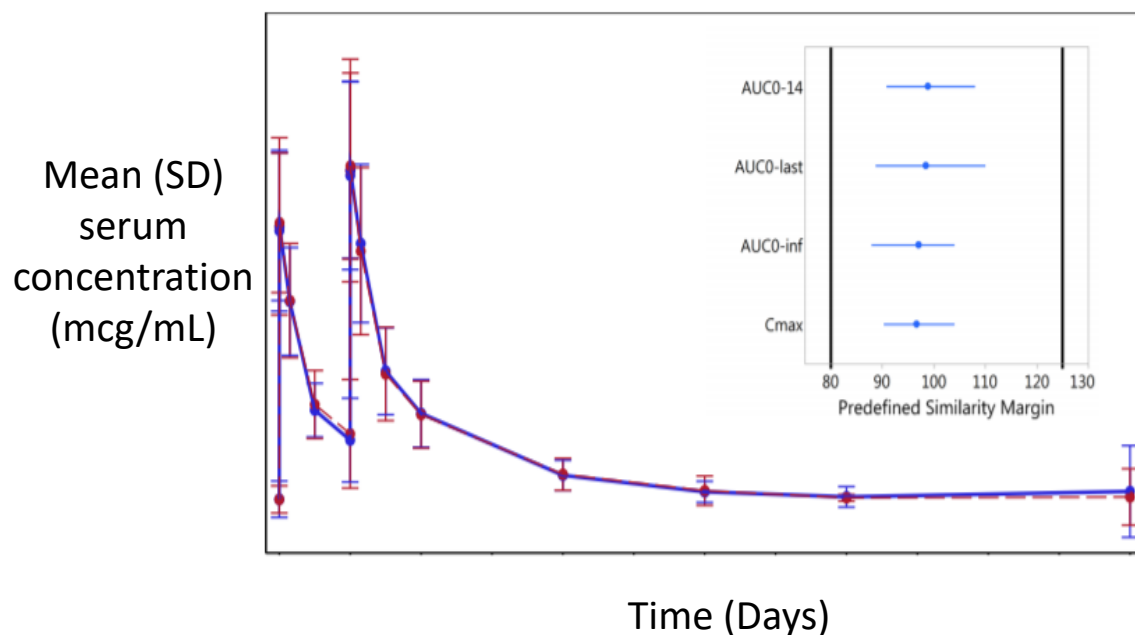
Euglycemic clamp study in healthy subjects

	Parameter	GMR (%)	90% CI
PK similarity	AUC0-24h	99.08	95.11 – 103.22
	Cmax	99.63	94.94 – 104.55
PD similarity	GIR AUC0-24h	94.92	86.95 – 103.62
	GIRmax	96.44	89.33 – 104.11

Clinical Program Example 2: CT-P10 vs US-Rituximab



PK Similarity Study in patients with rheumatoid arthritis using the therapeutic dosing



Comparative Clinical Study in patients with low tumor burden follicular lymphoma for comparing efficacy, safety, and immunogenicity

	CT-P10	US-Rituxan
Overall Response, n (%)	108/130 (83.1%)	104/128 (81.3%)
ORR Difference, (90% CI)	0.7981-1.0796	
Equivalence margin	0.83 – 1.17	
Immunogenicity	Similar	
Adverse events	Similar	

Rituximab-abbs (CT-P10) Licensed for Multiple Indications ^{1, 2}:

- Adult patients with Non-Hodgkin's Lymphoma (NHL)
- Adult patients with Chronic Lymphocytic Leukemia (CLL)
- Rheumatoid Arthritis (RA)
- Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA) in adult patients

The concept of extrapolation is based on:

- ✓ All available data and information in the biosimilar application
- ✓ FDA's previous finding of safety and efficacy for other approved indications for the reference product
- ✓ Knowledge and consideration of various scientific factors for each indication

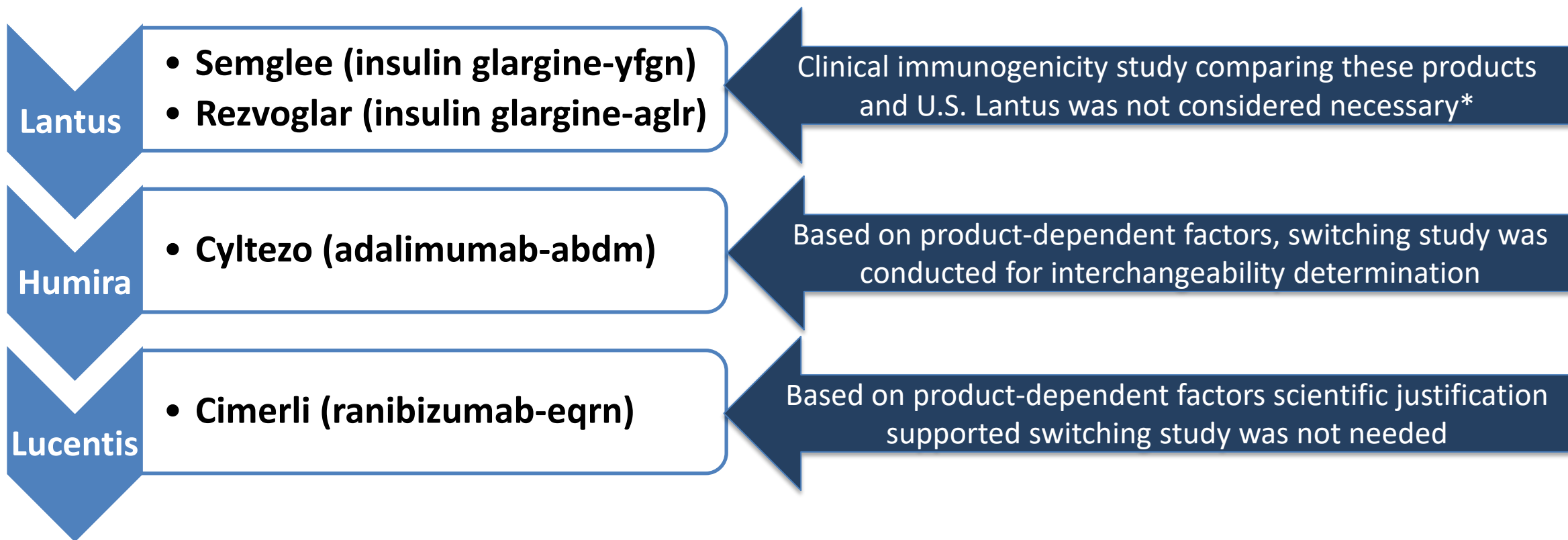


¹ See USPI for full indication text: [Nov 28, 2018 USPI](#)

² See USPI for full indication text: [Feb 04, 2022 USPI](#)

Interchangeable Biosimilars

To date, FDA has approved 4 interchangeable biosimilars to 3 different reference products



*Draft Guidance for Industry: Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products, 2019 <https://www.fda.gov/media/133014/download>; Review Documents available at: [Drugs@FDA: FDA-Approved Drugs](mailto:Drugs@FDA)

Switching Between Products – Literature Highlights & Conclusions



- Reviews* of randomized and real-world studies do not suggest that switching from a reference product to a biosimilar results in efficacy, safety, or immunological issues
- Reviews# of randomized and real-world studies show that single or multiple switches between the reference product and its biosimilars had no negative impact on efficacy, safety, or immunogenicity
- Nocebo effect: Some studies report higher discontinuations in switched patients based on patient-reported outcomes without changes in objective parameters
- **Based on available data from randomized and real-world studies, no differences are observed in efficacy, safety, or immunogenicity following one or more switches, with the exception of nocebo effects.**
- **Theoretical safety and immunological concerns with switching have not been demonstrated in patients**

*Selected publication: [Barbier et al. 2020](#) reviewed 178 studies with one or more switches between RP and BP totaling nearly 21,000 switched patients.

#Selected publication: [Kurki et al. 2021](#) includes analyses for 23 biosimilar mAb and fusion proteins and represents over 2 billion treatment days

Using Biosimilar and Interchangeable Products

Using Reference, Biosimilar, and Interchangeable Products



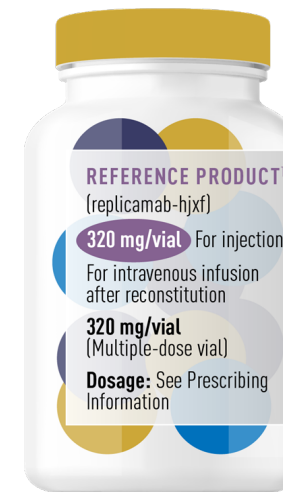
- Patients and health care providers *can be confident in the **safety** and **effectiveness** of a biosimilar and interchangeable product* and prescribe them by name, just as for the reference product.
- Biosimilar and interchangeable biosimilar products can be used in patients who have previously been 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).
- Interchangeable biosimilars may be substituted for the reference product without the intervention of the prescribing health care provider, subject to state laws.

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

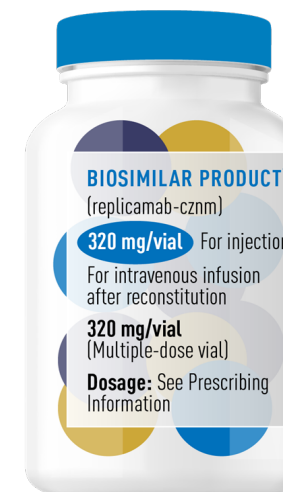
Biosimilar and Interchangeable Labeling

- The labeling summarizes the scientific information health care practitioners need for safe and effective use of the product.
- A biosimilar is not required to have the same labeling as its reference product (e.g., a biosimilar can be labeled for fewer than all conditions of use or there may be differences in storage/preparation, or presentation).
- Health care professionals are advised to review the labeling (i.e., prescribing information) of the biosimilar to determine the conditions of use (e.g., indications, dosing regimens) and routes of administration for which the biosimilar is approved.
- FDA recommends that Highlights of Prescribing Information contain a “Biosimilarity Statement” describing the product’s relationship to its reference product.

Reference Product



Biosimilar Product



Biosimilar Labeling cont.



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use **PROPRIETARY NAME** safely and effectively. See full prescribing information for **PROPRIETARY NAME**.

PROPRIETARY NAME (nonproprietary name) dosage form, route of administration, controlled substance symbol

Initial U.S. Approval: YYYY

NEXSYMEO (replicamab-cznm) is biosimilar* to JUNEXANT (replicamab-hjxf).

WARNING: TITLE OF WARNING

See full prescribing information for complete boxed warning.

- Text (4)
- Text (5.x)

RECENT MAJOR CHANGES

Section Title, Subsection Title (x.x) M/YYYY

Section Title, Subsection Title (x.x) M/YYYY

INDICATIONS AND USAGE

PROPRIETARY NAME is a (insert FDA established pharmacologic class text phrase) indicated for ... (1)

- Indication #1
- Indication #2
- Indication #3

DOSAGE AND ADMINISTRATION

- Text (2.x)
- Text (2.x)

DOSAGE FORMS AND STRENGTHS

- Strength 1, in a single-dose prefilled syringe
- Strength 1, in a single-dose prefilled autoinjector

CONTRAINDICATIONS

- Text (4)
- Text (4)

WARNINGS AND PRECAUTIONS

- Text (5.x)
- Text (5.x)

ADVERSE REACTIONS

Most common adverse reactions (incidence > x%) are text (6.x)

To report **SUSPECTED ADVERSE REACTIONS**, contact name of manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Text (7.x)
- Text (7.x)

USE IN SPECIFIC POPULATIONS

*Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of NEXSYMEO has been demonstrated for the condition(s) of use (e.g., indication(s), dosing regimen(s)), strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information.

Revised: M/YYYY

Key Takeaways



Fact: FDA-approved biosimilars are as safe and effective as their original biologic and you can expect biosimilars to have the same benefits and risks as the original biologic.

Fact: FDA's approval of an interchangeable biosimilar does not indicate a higher standard than biosimilarity (all interchangeables are also biosimilar), but that it underwent further evaluation to allow it to be substituted for the reference product without consulting the health care prescriber.

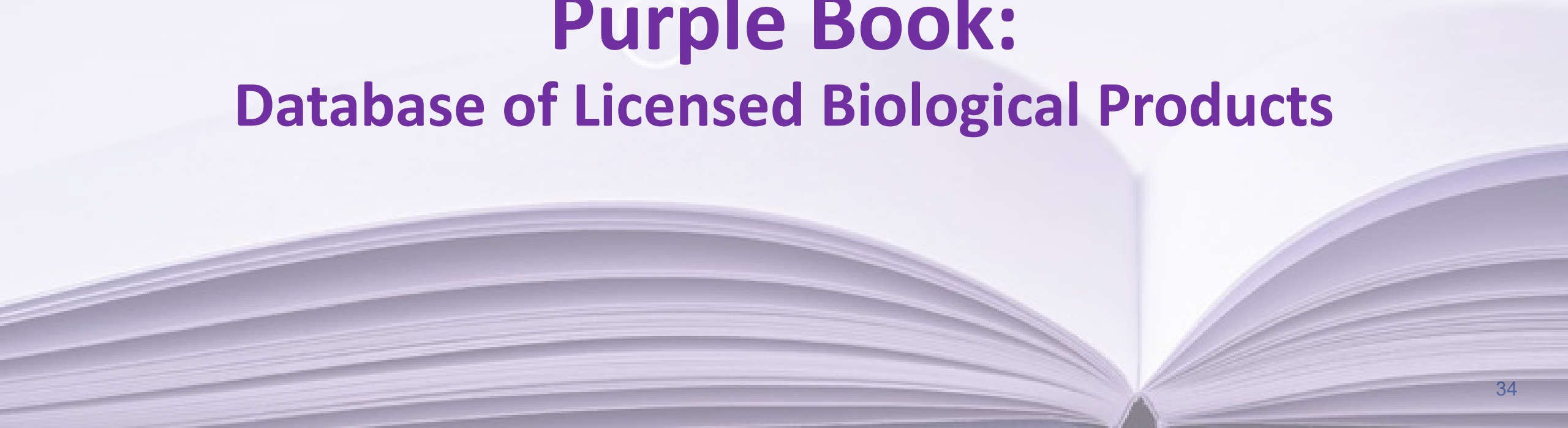
Fact: Patients and healthcare providers do not need to wait for a biosimilar product to be approved as an interchangeable product. Biosimilars are safe and effective, just like the reference product to which they were compared.

Fact: Biosimilar and Interchangeable labeling is not required to be the same as the reference product, but is expected to incorporate relevant data and information from reference product labeling.

Resources for Health Care Providers



Purple Book: Database of Licensed Biological Products

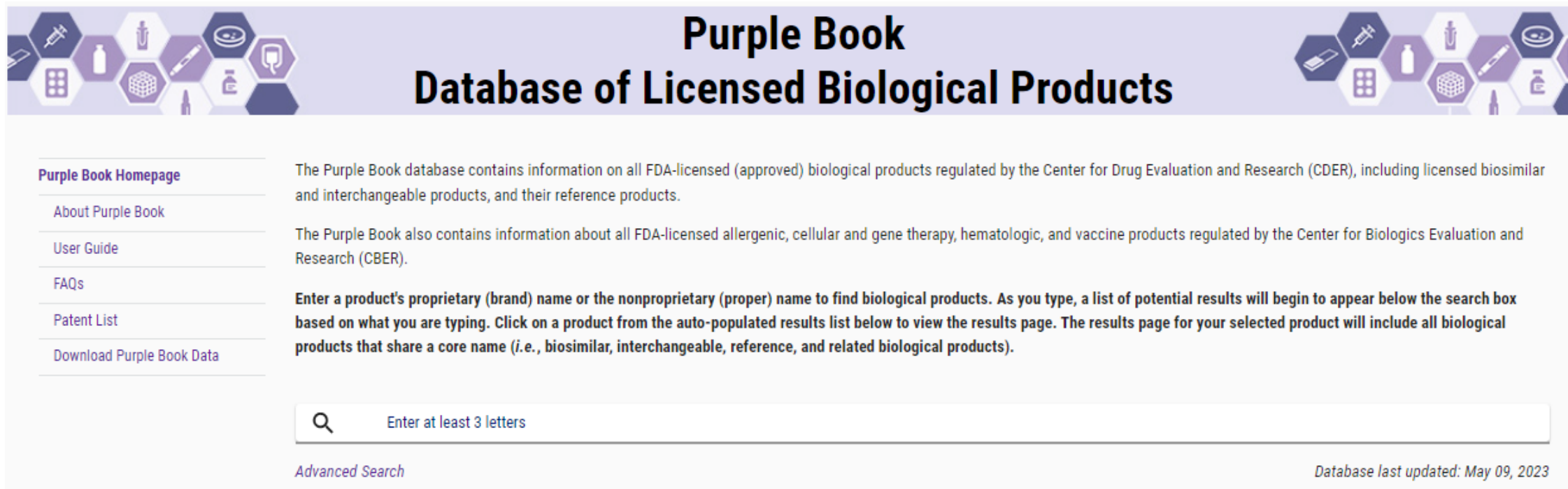


The Purple Book Database

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).

The database can be found at PurpleBookSearch.fda.gov



The screenshot shows the homepage of the Purple Book Database. At the top, there is a purple banner with the text "Purple Book Database of Licensed Biological Products" and decorative icons of biological products. Below the banner, on the left, is a navigation menu with links: "Purple Book Homepage", "About Purple Book", "User Guide", "FAQs", "Patent List", and "Download Purple Book Data". The main content area contains two paragraphs of text: "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." and "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).". Below this is a search box with a magnifying glass icon and the placeholder text "Enter at least 3 letters". At the bottom, there are two links: "Advanced Search" on the left and "Database last updated: May 09, 2023" on the right.

Purple Book's Features



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 for site location functions
- Auto-populated search results
- Additional advanced search filters
- Data download and export options
- Product label links
- Show/hide sortable data column options
- Searchable glossary of terms



Homepage & Simple Search

Purple Book Database of Licensed Biological Products

Purple Book Homepage

[About Purple Book](#)

[User Guide](#)

[FAQs](#)

[Patent List](#)

[Download Purple Book Data](#)

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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).



Product Name	BLA Number	Regulatory Pathway
Enbrel (etanercept)	103795	351(a)
Enbrel Mini (etanercept)	103795	351(a)
Erelzi (etanercept-szzs)	761042	351(k) Biosimilar
Erelzi Sensoready (etanercept-szzs)	761042	351(k) Biosimilar
Eticovo (etanercept-ykro)	761066	351(k) Biosimilar



[Advanced Search](#)

Database last updated: May 09, 2023

Simple Search Results

Proprietary Name
Erelzi
Erelzi Sensoready

Proper Name
etanercept-szzs

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.

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Home | Drug Databases | Drugs@FDA

Drugs@FDA: FDA-Approved Drugs

Biologic License Application (BLA): 761042
Company: SANDOZ

Medication Guide
Summary Review

Products on BLA 761042

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	BLD	RS
ERELZI	ETANERCEPT SZZS	50MG/0.5ML	INJECTABLE, INJECTION	Prescription	None	No	No
ERELZI	ETANERCEPT SZZS	50MG/0.5ML	INJECTABLE, INJECTION	Prescription	None	No	No

Showing 1 to 2 of 2 entries

Approval Date(s) and History, Letters, Labels, Reviews for BLA 761042

Labels for BLA 761042

Action Date	Submission	Supplemental Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Notes
09/11/2020	SUPPL-12	Efficacy-New Patient Population	Label (PDF)	
10/18/2019	SUPPL-10	Efficacy-New Indication	Label (PDF)	
01/28/2018	SUPPL-1	Labeling-Package Insert	Label (PDF)	
01/28/2018	SUPPL-1	Labeling-Medication Guide	Label (PDF)	
08/30/2018	ORIG-1	Approval	Label (PDF)	

Product Details



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	Proprietary Name	Status
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-szsz

Reference Product Proper Name
etanercept

Reference Product Proprietary Name
Enbrel

BLA Number
761042

Applicant
Sandoz Inc.

Original Approval Date
08/30/2016

Date of First Licensure

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Advanced Search

Purple Book Database of Licensed Biological Products

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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



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



Interchangeable Products



Biosimilar(s) ⓘ
No biosimilar data at this time.

Interchangeable(s) ⓘ

Reference Product(s) ⓘ

Interchangeable Product 1:
Proprietary Name: *Rezvoglar*
Proper Name: *insulin glargine-aglr*

Interchangeable Product 2:
Proprietary Name: *Semglee*
Proper Name: *insulin glargine-yfgn*

Interchangeable Product 3:
Proprietary Name: *Rezvoglar*
Proper Name: *insulin glargine-aglr*

Interchangeable Product 4:
Proprietary Name: *Semglee*
Proper Name: *insulin glargine-yfgn*

Reference Product 1:
Proprietary Name: *Basaglar*
Proper Name: *insulin glargine*








Reference Product 2:
Proprietary Name: *Lantus*
Proper Name: *insulin glargine*

Reference Product 3:
Proprietary Name: *Toujeo*
Proper Name: *insulin glargine*

Reference Product 4:
Proprietary Name: *Rezvoglar*
Proper Name: *insulin glargine-aglr*

Reference Product 5:
Proprietary Name: *Semglee*
Proper Name: *insulin glargine-yfgn*

Reference Product 6:
Proprietary Name: *Lantus*
Proper Name: *insulin glargine*


Proprietary Name Abrilada Proper Name adalimumab-afzb  PRODUCT LABEL	Proprietary Name Amjevita Proper Name adalimumab-atto  PRODUCT LABEL	Proprietary Name Hedliza Proper Name adalimumab-bwwd  PRODUCT LABEL
Proprietary Name Hulio Proper Name adalimumab-fkjp  PRODUCT LABEL	Proprietary Name Hynimoz Proper Name adalimumab-edez  PRODUCT LABEL	Proprietary Name Idacio Proper Name adalimumab-aacf  PRODUCT LABEL
Proprietary Name Yasimry Proper Name adalimumab-aqyh  PRODUCT LABEL		

Interchangeable Products, Continued



Proprietary Name
Cyltezo


Proper Name
adalimumab-adbm



PRODUCT LABEL

Proprietary Name
Cyltezo


Proper Name
adalimumab-adbm



PRODUCT LABEL

Proprietary Name
Humira


Proper Name
adalimumab



PRODUCT LABEL

Proprietary Name
Humira

Proper Name
adalimumab



PRODUCT LABEL

Glossary of Terms



An official website of the United States government [Here's how you know](#)

U.S. FOOD & DRUG ADMINISTRATION

Purple Book Glossary

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 products will 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 product page for your selected product will include all biological products that share a core name (i.e., biosimilar, interchangeable, reference product).

[Advanced Search](#)

Glossary

Search for a term...

Example: "Biosimilar"

3

- 351(a)
- 351(k) Biosimilar
- 351(k) Interchangeable

A

- Applicant (sponsor)
- Approval Date

B

- Biological Product



Glossary

Biosimilar Education and Outreach

Education and Outreach

- FDA is committed to developing effective communications to improve understanding of biosimilars among patients, health care providers and payors
 - **Engaging** with health care professional and patient stakeholders
 - **Developing** educational materials for health care prescribers, pharmacists, and patients
- Education is an undertaking that requires **multi-stakeholder engagement**

FDA is committed to fulfilling their important role as one of many stakeholders

Communication Challenges

- Lack of awareness and information gaps
- Low health literacy
- Concerns about safety and efficacy
- Lack of trust
- Concerns about cost and equivalency to existing treatment
- Negative perceptions and expectations leading to nocebo effect

Health Care Provider Materials

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 Biologics Price Competition and Innovation Act of 2009 created an abbreviated 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 evaluation so that health care providers and patients can be confident of the safety, effectiveness, and quality of these products.
- A biosimilar is a biologic that is highly similar to and has no clinically meaningful differences from an existing FDA-approved biological medication, called a reference product.
- A reference product is approved in a standalone application that must contain all data and information necessary to demonstrate the product's safety and effectiveness.
- The goal of a biosimilar development program is to demonstrate biosimilarity between the proposed biosimilar and its reference product, not to independently establish the safety and effectiveness of the proposed biosimilar. This generally means that biosimilar manufacturers do not need to conduct as many expensive and lengthy clinical trials.
- The abbreviated pathway involves an extensive structural and functional comparison of the biosimilar and the reference product.
- Because biologics are usually made in cells, even with identical amino acid sequences, there will be inherent variations (for example, glycosylation) that result from the manufacturing process in any batch or dose.
- As part of the approval process for both reference products and biosimilars, FDA assesses a manufacturer's strategy to control for the pattern and degree of variations between different batches so that safety and effectiveness don't change.
- FDA monitors the safety and effectiveness of all medications after their approval. This involves inspecting manufacturing facilities and reviewing manufacturer, provider, and patient safety reports made to FDA.

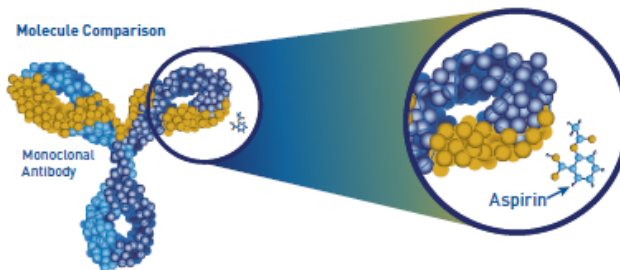


Overview of Biosimilar Products

Biosimilars are safe and effective biological medications for treating many illnesses, 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

- Biological products, or biologics, are generally large, complex molecules that are made from living sources such as bacteria, yeast, and animal cells. On the other hand, drugs made from chemicals are smaller molecules and easier to copy.
- Because they generally come from living organisms, biologics inherently contain many slight variations from batch to batch, and their structures are generally more complex than those of other medications. As a result, biologics are often more complicated to purify, process, and manufacture.
- There are many types of biologics approved for use in the United States, including therapeutic proteins; vaccines; blood, blood components, and their derivatives; allergenic products; and monoclonal antibodies.



Interchangeable Biological Products

An interchangeable biological product is a biosimilar that meets additional requirements and may be substituted for the reference product at the pharmacy, depending on state pharmacy laws. Interchangeable biological products (also called interchangeable biosimilars or interchangeable products) may help increase patient access to biologics.

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.
- Not all biosimilars are interchangeable. Companies must submit an application with adequate information to support an interchangeability determination for their product to be approved as an interchangeable biosimilar.

Pharmacy-Level Substitution



Interchangeable Biosimilar Approval Process

- Unlike a reference product, which is approved in a standalone application, all biosimilar and interchangeable biosimilars are approved through an abbreviated pathway that compares the product to the reference product to show biosimilarity.
- For approval as an interchangeable biosimilar, manufacturers must provide additional data that reflect how the interchangeable biosimilar may be used in the marketplace with patients. Like generic drugs, patients receiving their medications through their pharmacies may switch between a brand-name biologic and an interchangeable biosimilar.
- To assess the safety of switching, manufacturers generally conduct studies in which patients alternate between the reference product and the interchangeable biosimilar and compare those patients to patients who are just being treated with the reference product. The results must show no decrease in effectiveness or increase in safety risk associated with switching.
- While this additional information helps FDA to determine the safety of pharmacy-level substitution, this does not mean that an interchangeable biosimilar is safer or more effective than other biosimilars.

All biological products are approved only after they meet FDA's rigorous approval standards, so health care professionals and patients can be confident in the safety and effectiveness of a biosimilar product, whether or not it has also been approved as an interchangeable biosimilar, just as they would be for a reference product.

Explore FDA's biosimilar resources for health care professionals at www.fda.gov/biosimilars.

FDA Biosimilar Materials for Patients



www.fda.gov/drugs/biosimilars/basics-patients

- English and Spanish fact sheets, infographics, articles, and more

Making more treatment options available ...

FDA U.S. FOOD & DRUG ADMINISTRATION

Biosimilars:
What Patients With Diabetes Need To Know

Biosimilars are types of biologic medication that are **safe and effective** for treating many chronic and severe conditions, including diabetes, as well as:

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

The regulation of insulin as a biologic allows multiple companies to make biosimilar versions of "brand name" insulins, similar to how generics are versions of brand name drugs.

A biosimilar is very similar, but not identical, to an original biologic (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 their 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

For more information on biosimilars, visit www.FDA.gov/biosimilars and talk to your doctor to learn more.

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.

Has insulin always been a biologic?

Although insulin is made in living cells, it was historically regulated as a drug made from chemicals. Insulin and other drugs that meet the criteria for a biologic are now regulated as biologics. This does not change the ingredients of insulin or how you obtain medication at the pharmacy.

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.**

- 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

FDA Biosimilar Materials in Spanish

Conceptos básicos de los Biosimilares para los pacientes

Artículos en español

Alimentos y Bebidas

Cosméticos

Dispositivos Médicos

Dispositivos que Emiten Radiación

Fraude en la Salud

Medicamentos

Nutrición

Productos de Tabaco

Productos Veterinarios

Salud de la Mujer

Salud Infantil

Vacunas, Sangre y Productos Biológicos

Los biosimilares

U.S. FOOD & DRUG ADMINISTRATION

English

La Administración de Alimentos y Medicamentos de los EE.UU. (FDA, por sus siglas en inglés) ha aprobado medicamentos biosimilares para tratar enfermedades como el cáncer, la enfermedad de Crohn, la colitis, la artritis reumatoide, la psoriasis y otras.

Pero, ¿qué son los medicamentos biosimilares y biológicos intercambiables? Para

¿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:



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:



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:



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:

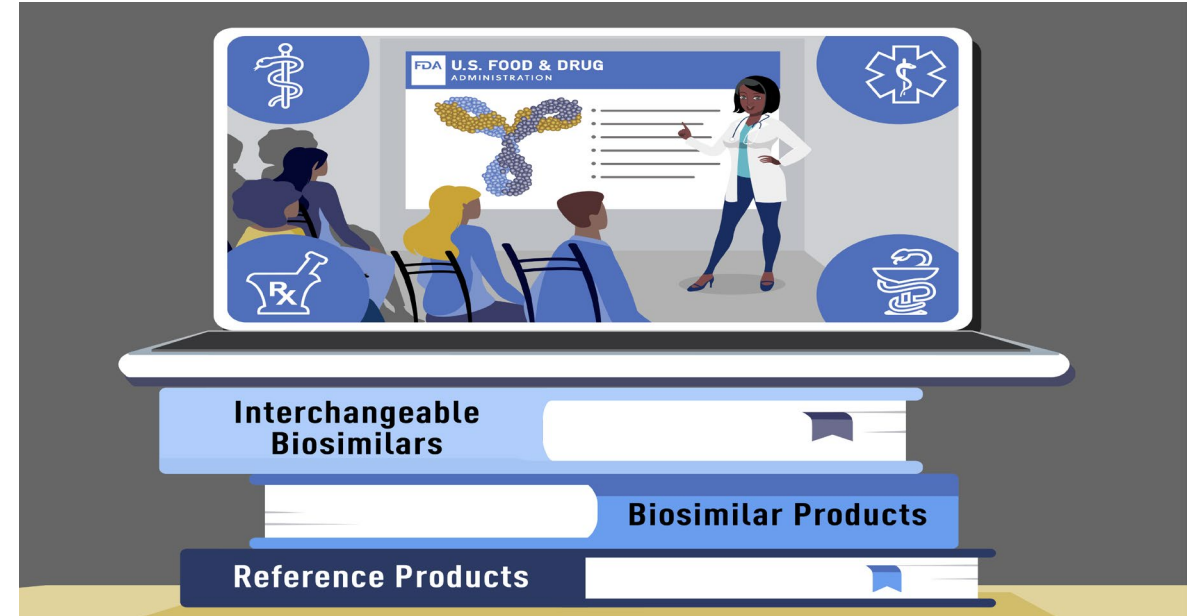


Visite www.FDA.gov para conocer más acerca de los biosimilares.



Curriculum for Health Care Degree Programs

- The Biosimilar Curriculum Toolkit contains multiple types of resources to assist teaching faculty who would like to integrate topics about biosimilars into the training they provide students.
- The materials included in the toolkit were designed to meet a variety of teaching needs and contain foundational and more in-depth information by levels.
 - Level 1 is foundational and provides a high-level overview of foundational topics.
 - Level 2 materials provide an in-depth look at scientific and regulatory topics and their practical applications.
- Materials include information sheets, slide decks, videos, case studies, discussion questions, and more.



Topics covered:

- Biologics, biosimilars, and interchangeability
- The approval pathways for biological products
- Manufacturing and variation in biological products
- Labeling and prescribing biosimilar and interchangeable biosimilar products



Medscape Continuing Education

FDA is supporting the development of a series of continuing education (CE) courses through Medscape about biosimilar and interchangeable products. This includes 4 courses in 2022 and a dedicated website for the content.

Medscape Thursday, November 17, 2022

NEWS & PERSPECTIVE DRUGS & DISEASES **CME & EDUCATION** ACADEMY VIDEO DECISION POINT

NAVIGATING THE MAZE: EXPERT GUIDANCE ON UNDERSTANDING AND INTEGRATING BIOSIMILARS IN PRACTICE

From [Medscape Education](#)

CME / ABIM MOC / CE

Putting the Patient Into Perspective: Strategies for Educating Patients About Biosimilars

Authors: Stephen B. Hanauer, MD

CME / ABIM MOC / CE Released: 8/22/2022 Valid for credit through: 8/22/2023

Medscape Thursday, September 1, 2022

NEWS & PERSPECTIVE DRUGS & DISEASES **CME & EDUCATION** ACADEMY VIDEO DECISION POINT

NAVIGATING THE MAZE: EXPERT GUIDANCE ON UNDERSTANDING AND INTEGRATING BIOSIMILARS IN PRACTICE

From [Medscape Education Oncology](#)

CME / ABIM MOC / CE

Test Your Skill: Incorporating Biosimilars Into the Management of Patients With Immunological Conditions

Authors: Steven Feldman, MD, PhD

CME / ABIM MOC / CE Released: 6/15/2022 Valid for credit through: 6/15/2023

Medscape Thursday, September 1, 2022

NEWS & PERSPECTIVE DRUGS & DISEASES **CME & EDUCATION** ACADEMY VIDEO DECISION POINT

NAVIGATING THE MAZE: EXPERT GUIDANCE ON UNDERSTANDING AND INTEGRATING BIOSIMILARS IN PRACTICE

From [Medscape Education Family Medicine](#)

CME / ABIM MOC / CE

Biosimilars 101: A Primer for Your Practice

Authors: Jonathan Kay, MD

CME / ABIM MOC / CE Released: 5/19/2022 Valid for credit through: 5/19/2023

Medscape Thursday, September 1, 2022

NEWS & PERSPECTIVE DRUGS & DISEASES **CME & EDUCATION** ACADEMY VIDEO DECISION POINT

NAVIGATING THE MAZE: EXPERT GUIDANCE ON UNDERSTANDING AND INTEGRATING BIOSIMILARS IN PRACTICE

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Authors: Stephen B. Hanauer, MD

CME / ABIM MOC / CE Released: 8/22/2022 Valid for credit through: 8/22/2023

Stakeholder Engagement

FDA works with government and non-government stakeholders to support uptake and utilization of biosimilars.

- USP/FDA Infographic on biosimilars and quality
- FDA/ FTC educational resource for patients about biosimilar treatment options

Conducting stakeholder outreach and offering education to stakeholders including patient advocacy organizations, medical and professional associations, payors, pharmacy organizations, and state and federal governments partners.

Biosimilars: Are they the same quality?

What are biologics?

Biologics (also called biological products) include a **wide range of products** such as vaccines, monoclonal antibodies, blood components, allergenics, gene therapy, tissues, and proteins.

Biologics are medicines that generally come from **living organisms**, which can include animal cells and microorganisms, such as yeast and bacteria.

They are used to treat a variety of diseases and conditions, such as **cancer, kidney diseases, and autoimmune diseases.**

What are biosimilars?

A biosimilar is a biologic that is **highly similar** to another biologic that's already FDA-approved, called a reference product. Biosimilars have **no clinically meaningful differences** from their reference product in terms of **safety, purity, and potency.**

Biosimilars have the same:

- Route of administration to patients
- Strength and dosage form
- Potential side effects

Biosimilars are approved for many biologic reference products², including:

▶ Avastin	▶ Humira	▶ Lucentis	▶ Remicade
▶ Epogen/Procrit	▶ Herceptin	▶ Neulasta	▶ Rituxan
▶ Enbrel	▶ Lantus	▶ Neupogen	

Biosimilars can improve patient access to quality medicines

Biosimilars are versions of brand name biologics that may offer more affordable treatment options to patients, similar to generic drugs.

Are you on a biologic medication?

What you need to know about biosimilar treatment options.

The U.S. Food and Drug Administration (FDA) has approved many biologics (also called biological products), which are medications generally made from living sources like bacteria and yeast. Biologics treat many conditions like arthritis, diabetes, kidney conditions, cancer, macular degeneration, and chronic skin and bowel diseases, such as psoriasis, Crohn's disease, and ulcerative colitis.

But biologics are often expensive and can be unaffordable, especially for people using several medications. If you're currently using a biologic and you're concerned about cost, you and your health care provider may want to talk about switching to a biosimilar. A biosimilar is an FDA-approved biologic that is highly similar to and has no clinically meaningful differences from a biologic previously approved by FDA, which is sometimes described as the original biologic or reference product. Like generic drugs, biosimilars may save you money and are as safe and effective as the original biologic.

Some patients and health care providers might worry that biosimilars are not as safe or effective as the original biologic or that an interchangeable biosimilar is better than a biosimilar that is not an interchangeable biosimilar. Unwarranted concerns may discourage patients and their doctors from using or switching to a biosimilar, so it's important to find out the facts.

How is a biologic like other drugs?

FDA-approved biologics, like other drugs FDA approves, are safe and effective medications for treating many illnesses. However, biologics are usually made from living sources such as proteins, living cells, and microorganisms such as bacteria or yeast. They usually are more complex than other drugs, and more complicated to make.

For more information on biosimilars, visit www.FDA.gov/biosimilars and talk to your doctor to learn more.

Future Education and Outreach Plans



- Materials and resources for **patients**:
 - Videos
 - Additional infographics and graphics
- Materials and resources for **health care providers**:
 - Videos
 - More continuing Education course options through Medscape
 - Updated educational curriculum/teaching resources for HCP schools
- Continue work with multiple stakeholders to increase educational opportunities and ensure unbiased, truthful information about biosimilars is available.

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.



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11. Guidance for Industry: Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products. November 2019. <https://www.fda.gov/media/133014/download>



Questions?

Thank you

Visit www.FDA.gov/biosimilars to learn more about biosimilars.