Biosimilar and Interchangeable Biological Products: An Overview of Scientific Concepts and Practical Resources

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FDA U.S. FOOD & DRUG ADMINISTRATION

Presenters

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Sabiha Khan, MD

Sabiha Khan, MD, is a Scientific Reviewer at the U.S. Food and Drug Administration's (FDA's) Office of Therapeutic Biologics and Biosimilars (OTBB). She is a part of the interdisciplinary team which supports communicating clear, consistent scientific advice for biosimilar and interchangeable product development. Dr. Khan completed her rheumatology fellowship at the Johns Hopkins University, prior to which she completed her residency in internal medicine at Rush University Medical Center. She received her medical degree from the University of Virginia, and her Bachelor of Science in Biological Psychology from the College of William and Mary.

After completing her rheumatology fellowship, Dr. Khan established and grew her practice in general rheumatology with Johns Hopkins Community Physicians and also served as the Director of the Rapid Arthritis Care and Evaluation Clinic for the Division of Rheumatology at Johns Hopkins Hospital. Dr. Khan joined the Agency as a medical officer with the Division of Pulmonary, Allergy, and Rheumatology Products in 2020. Since then, she has worked in the Division of Rheumatology and Transplant Medicine (DRTM) and in OTBB.

Sarah Ikenberry, MA

Ms. Sarah Ikenberry is the Associate Director for Stakeholder Engagement and Clinical Outcomes at the Office of Therapeutic Biologics and Biosimilars (OTBB) in the U.S. Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research (CDER). She leads OTBB's stakeholder engagement and education program, and FDA's activities related to biosimilars communication activities. This includes providing communication advice and support to senior leaders and the agency about communicating strategic priorities, initiatives, and educational information about biosimilar and interchangeable products. Ms. Ikenberry received her Master of Arts in Communication from Johns Hopkins University.

Disclosures

- Dr. Khan and Ms. Ikenberry have no relevant financial or non-financial relationships to disclose relating to the content of this activity.
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Learning Objectives

At the conclusion of this activity, participants will be able to:

1. Describe how biologics differ from small molecules (size, complexity, inherent variation) and explain why some biologics cannot be copied exactly.
2. Compare and contrast the development, statutory requirements, and approval process for new biologics and for biosimilars/interchangeables.
3. Explain the requirements for generics and biosimilars/interchangeables.
4. Identify resources available for health care professionals to learn more about biosimilar and interchangeable products through the Purple Book Database Licensed Biological Products and other FDA educational resources.

Overview

- U.S. Biosimilars Market Overview
- Scientific Concepts and Regulatory Framework
- Overview of Biosimilar Development Programs
- Using biosimilar and interchangeable products
- Biosimilar Educational Materials and Resources

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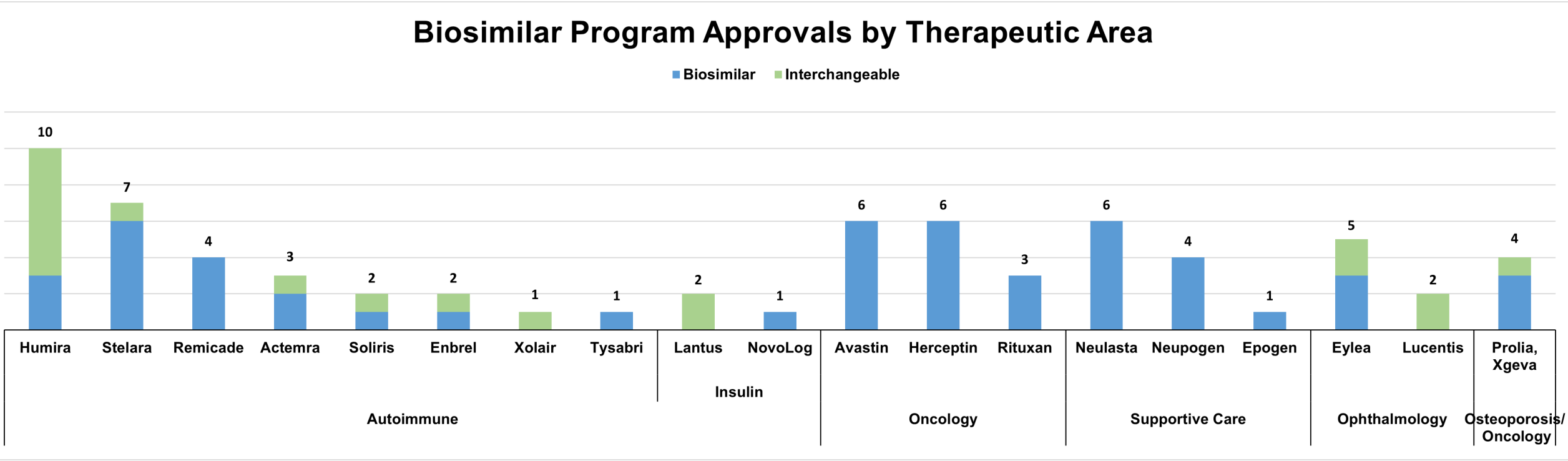
BIOSIMILAR AND INTERCHANGEABLE PRODUCTS

U.S. Biosimilars Market Overview



Approvals

70 Total Approvals
51 Biosimilar
19 Interchangeable

19 Reference Products (RP)
49 Products Marketed
12 Unique RPs Marketed

(FDA, 2025)

Reference Products and Approved Biosimilars as of April 9, 2025 (70 total)

Oncology

Avastin
Mvasi (bevacizumab-awwb)
Zirabev (bevacizumab-bvzr)
Alymsys (bevacizumab-maly)
Vegzelma (bevacizumab-adcd)
Avziri (bevacizumab-tnjn)
Jobevne (bevacizumab-nwgd)

Herceptin
Ogivri (trastuzumab-dkst)
Herzuma (trastuzumab-pkrb)
Ontruzant (trastuzumab-dttb)
Trazimera (trastuzumab-qyyp)
Kanjinti (trastuzumab-anns)
Hercessi (trastuzumab-strf)

Rituxan
Truxima (rituximab-abbs)
Ruxience (rituximab-pvvr)
Riabni (rituximab-arrx)

Supportive Care

Neulasta
Fulphila (pegfilgrastim-jmdb)
Udenyca (pegfilgrastim-cbqv)
Ziextenzo (pegfilgrastim-bmez)
Nyvepria (pegfilgrastim-apgf)
Fylnetra (pegfilgrastim-pbbk)
Stimufend (pegfilgrastim-fpgk)

Neupogen
Zarxio (filgrastim-sndz)
Nivestym (filgrastim-aafi)
Releuko (filgrastim-ayow)
Nypozi (filgrastim-txid)

Epogen/Procrit
Retacrit (epoetin alfa-epbx)

Osteoporosis/ Oncology

Prolia and Xgeva
Jubbonti and Wyost* (denosumab-bbdz)
Ospomyv and Xbryk (denosumab-dssb)
Stoboclo and Osenvelt (denosumab-dmwo)
Bomyntra and Conexxence (denosumab-bnht)

Autoimmune

Humira
Amjevita* (adalimumab-atto)
Cyltezo* (adalimumab-adbm)
Hyrimoz* (adalimumab-adaz)
Hadlima* (adalimumab-bwwd)
Abrilada* (adalimumab-afzb)
Hulio* (adalimumab-fkjp)
Yusimry (adalimumab-aqvh)
Idacio (adalimumab-aacf)
Yuflyma* (adalimumab-aatv)
Simlandi* (adalimumab-ryvk)

Tysabri
Tyruko (natalizumab-sztn)

Stelara
Wezlana* (ustekinumab-auub)
Selarsdi* (ustekinumab-aekn)
Pyzchiva* (ustekinumab-ttwe)
Otulfi* (ustekinumab-aauz)
Imuldosa (ustekinumab-srlf)
Yesintek* (ustekinumab-kfce)
Steqeyma* (ustekinumab-stba)

Remicade
Inflectra (infliximab-dyyb)
Renflexis (infliximab-abda)
Ixifi (infliximab-qbtx)
Avsola (infliximab-axxq)

Actemra
Tofidence (tocilizumab-bavi)
Tyenne (tocilizumab-aazg)
Avtozma* (tocilizumab-anoh)

Novolog
Merilog (insulin aspart-szjj)

Lantus
Semglee* (insulin glargine-yfgn)
Rezvoglar* (insulin glargine-aglr)

Enbrel
Erelzi (etanercept-szzs)
Eticovo* (etanercept-ykro)

Soliris
Bkmev* (eculizumab-aeeb)
Epysqli (eculizumab-aagh)

Xolair
Omlyclo* (omalizumab-igec)

Ophthalmology

Eylea
Opuviz* (aflibercept-yszy)
Yesafili* (aflibercept-jbzf)
Ahzantive (aflibercept-mrbb)
Enzeevu (aflibercept-abzv)
Pavblu (aflibercept-ayyh)

Lucentis
Byooviz* (ranibizumab-nuna)
Cimerli* (ranibizumab-eqrn)

25 Reference Products

49 Marketed

Note: Products with an asterisk have the 351(k) Interchangeable designation.

Biosimilars Are Delivering Savings and Expanding Patient Access

Biosimilar savings since 2015

$36 BILLION

Biosimilars have been used in almost **2.7 BILLION DAYS** of patient therapy and have resulted in more than **495 MILLION INCREMENTAL DAYS** of therapy

Biosimilar competition is driving lower prices among biosimilars and their reference products

SOURCE: AAM / 2024 U.S. Generic and Biosimilar Medicines Savings Report (https://accessiblemeds.org/resources/blog/2024-savings-report)

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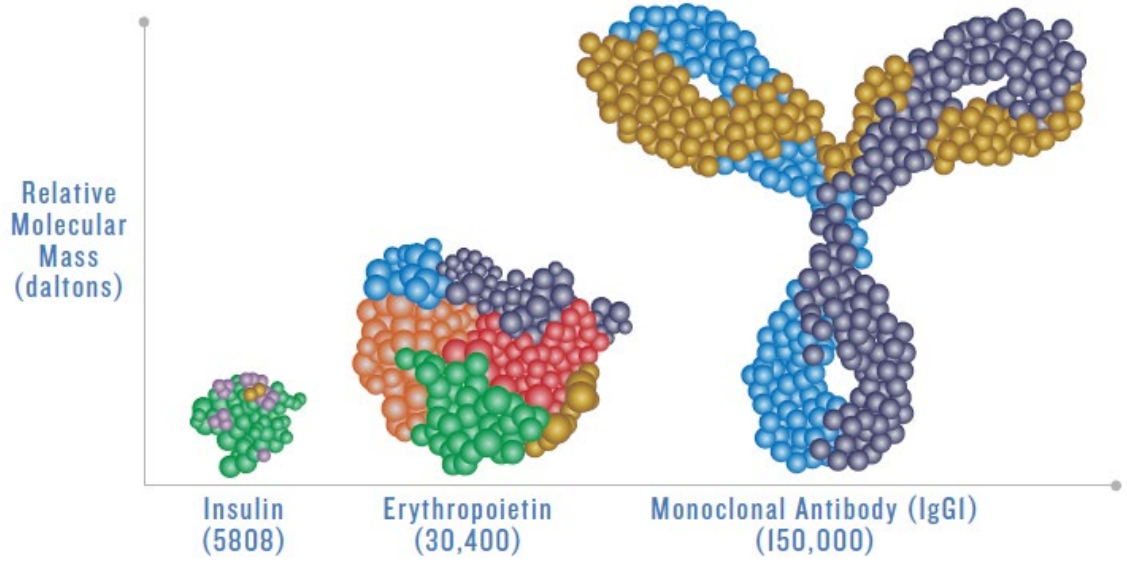
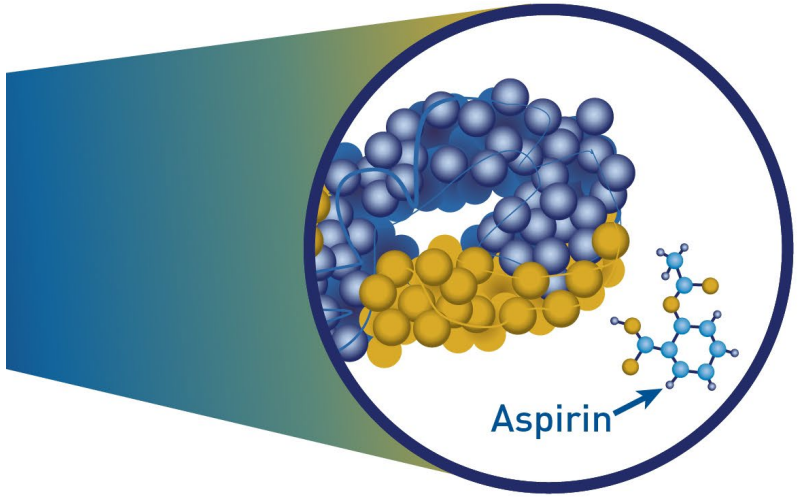
BIOSIMILAR AND INTERCHANGEABLE PRODUCTS

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

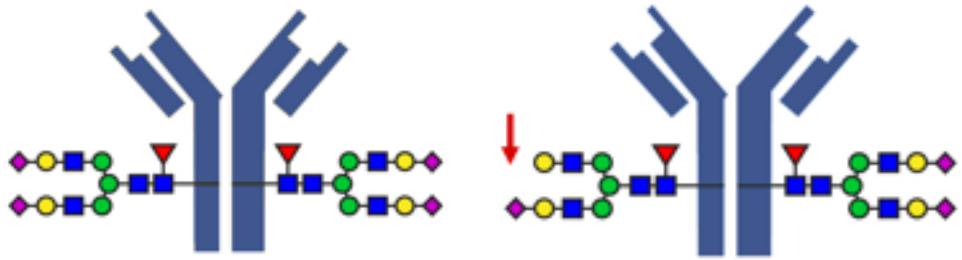


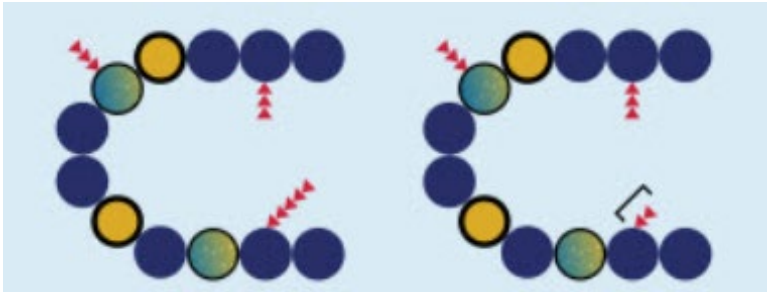


(Modified from Mellstedt H, EJC Supplements II, 2013, 3, I – II)

Therapeutic Proteins: Complexity

- Cells can make exact copies of a protein in terms of its amino acid sequence, 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 establish processes that produce a consistent mix of variants across batches of their products and over time





(FDA, n.d.)

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)

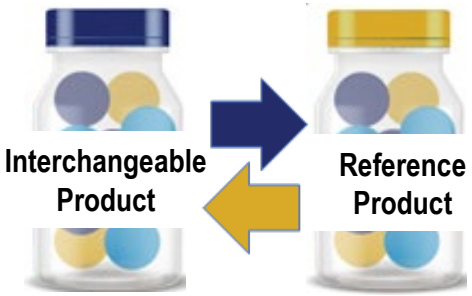
Key Definitions from the BPCI Act

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

General Requirements

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

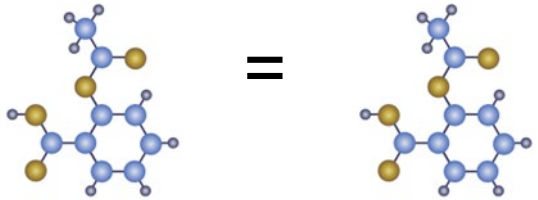
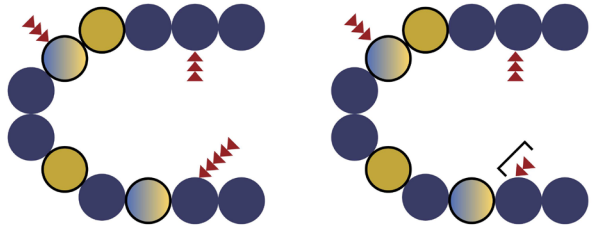
- Is **biosimilar** to a reference product
  - **Highly similar to and has no clinically meaningful differences from the** FDA-approved reference product
- Utilizes the **same mechanism(s) of action** for the proposed condition(s) of use -- but only to the extent the mechanism(s) are known for the reference 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

Regulatory Framework for Generics vs. Biosimilars

	Generic Drug (Orange Book)	Biosimilar Biologic (Purple Book)
Assessment	"Same" Active Ingredient Pharmacokinetic (PK) Bioequivalence	"Highly Similar" No Clinically Meaningful Differences
Illustrative Schematic of Product Comparisons Note: Comparative analytical data expected for both products		 Brackets are used to show sites with minor variations. *Reproduced with permission from the European Medicines Agency*
Clinical Pharmacology Studies	Compare PK, when applicable	Compare PK, and when applicable, pharmacodynamic (PD)
Other Clinical Study(ies)	Rarely, when PK is not applicable	Assess immunogenicity; may further evaluate safety and efficacy

Both are "abbreviated" development pathways that have distinct statutory requirements and scientific considerations supporting their approval.

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DEVELOPING BIOSIMILARS

Overview of Biosimilar Development Programs

Comparative Analytical Assessment (CAA) 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 mechanism of action(s)

Key Takeaways about Analytical Comparisons

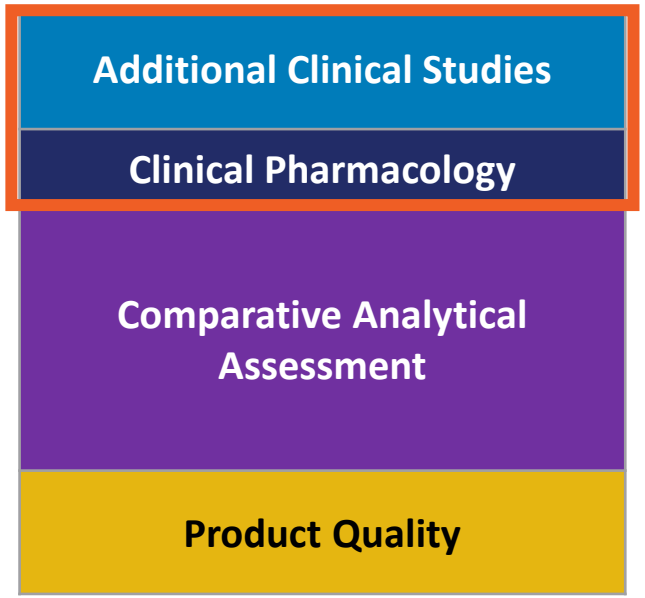
- Normal and expected for **all biological products** to have minor differences (i.e., inherent variations) within each dose and between batches
- Biosimilars can have minor differences from their reference products in clinically inactive components
- Analytical comparisons are state-of-the-art, precise, and reliable, conferring high confidence about the similarity of a proposed product to its reference product
- No matter the small molecular variations observed, biosimilars are analytically highly similar to their reference product and so they will behave the same as the reference product clinically, **with the same treatment risks and benefits**

Role of Clinical Studies

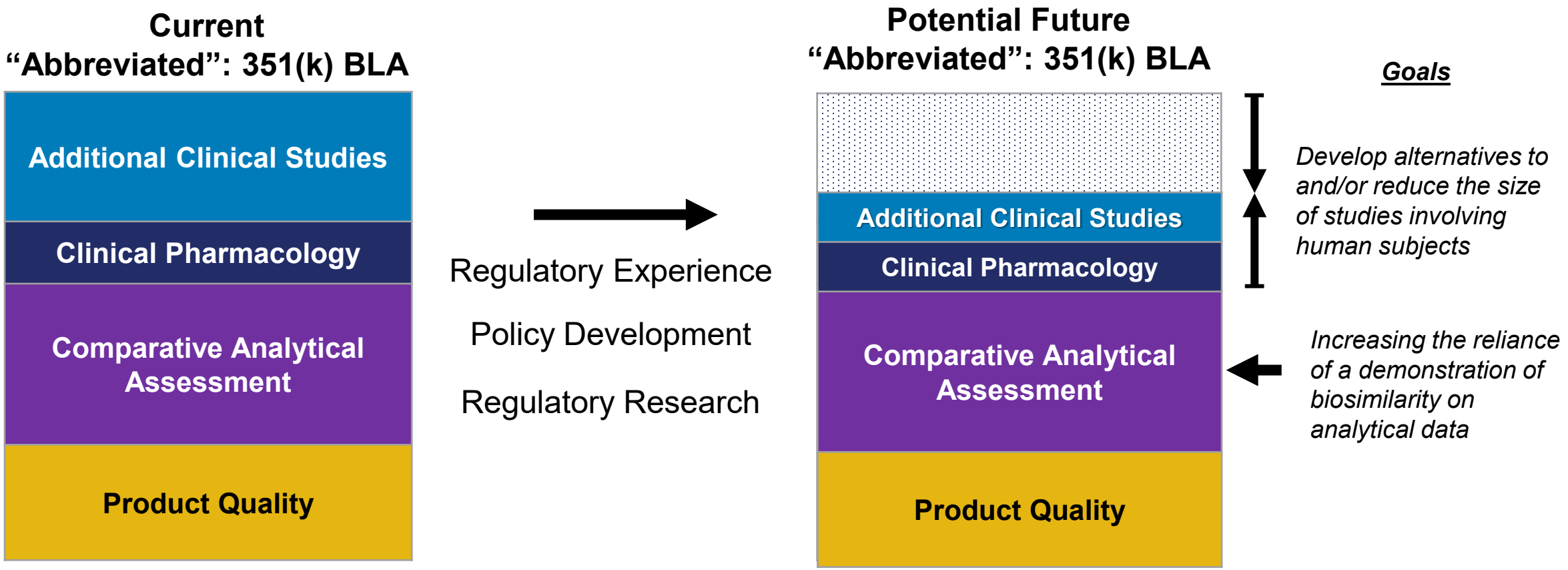
- As a scientific matter, FDA expects an adequate clinical PK, and PD if relevant, comparison between the proposed biosimilar product and reference product and a clinical immunogenicity assessment
- Additional clinical studies are not considered "pivotal" in the way Phase 3 clinical trials are for standalone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

Key Takeaways about Clinical Comparisons

- Often some baseline scientific expectations for a given class of products (e.g., showing of PK similarity, where relevant) but no one-size-fits-all approach
- Applicants may choose to do or submit more data than what FDA expects to support approval
- More clinical data in a package does not mean that one approved 351k product is “better” than another approved 351k product



FDA Efforts to Streamline Biosimilar Development



VIRTUAL

Increasing the Efficiency of Biosimilar Development Programs--Reevaluating the Need for Comparative Clinical Efficacy Studies

SEPTEMBER 12 - 13, 2023

Date: September 12 - 13, 2023

Day1: Tue, Sep 12 7:00 AM - 10:00 AM ET

Day2: Wed, Sep 13 7:00 AM - 10:00 AM ET

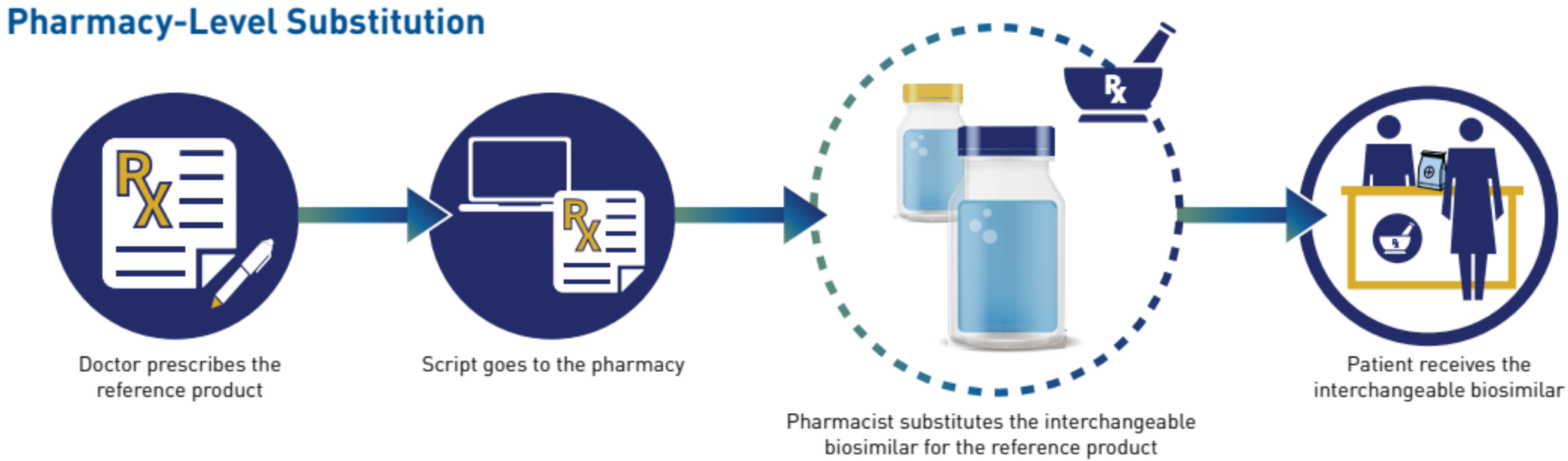
Increasing the Efficiency of Biosimilar Development Programs--Reevaluating the Need for Comparative Clinical Efficacy Studies - 09/12/2023 | FDA

FDA and the International Pharmaceutical Regulators Program (IPRP) hosted a virtual workshop "Increasing the Efficiency of Biosimilar Development Programs--Reevaluating the Need for Comparative Clinical Efficacy Studies" on September 12-13, 2023.

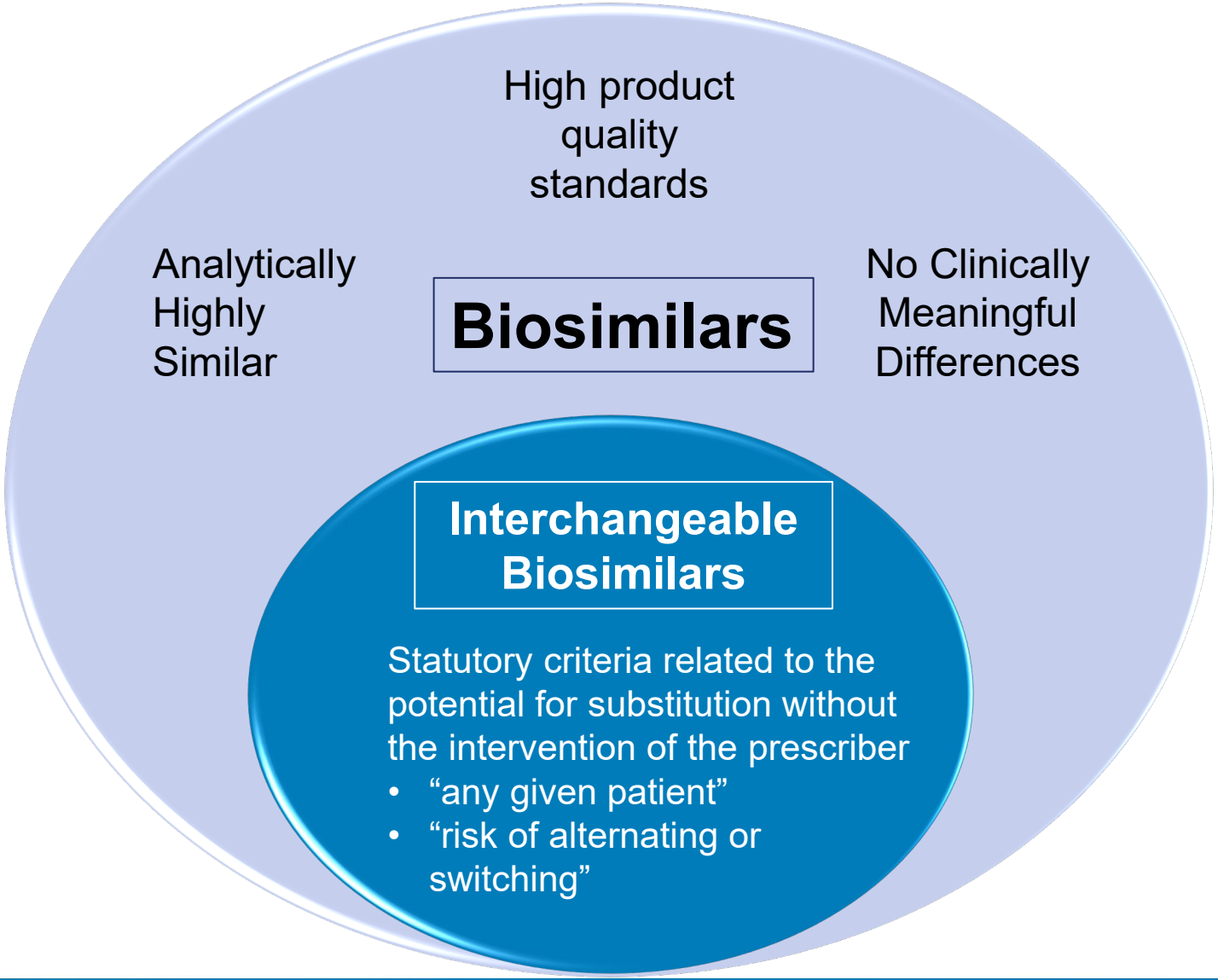
- **Recordings and slides from public portion of the meeting online**
- **Regulator only sessions Sept. 19-21, 2023**
- **Workshop Summary**

Why Seek Interchangeability?

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



Biosimilars and Interchangeable Biosimilars



- Applicants can request licensure as a biosimilar or interchangeable biosimilar
- 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
- FDA initially recommended switching studies to assess PK, safety and immunogenicity between 2 treatment arms:
  - Patients on reference product only
  - Patient on reference product → proposed biosimilar (1 or more times)

PLOS ONE

3 October 2023
published online and
freely available

Safety outcomes when switching between biosimilars and reference biologics A systematic review and meta-analysis

Thomas M. Herndon[1] , Cristina Ausin[1] , Nina N. Brahme[1] , Sarah J. Schrieber[1] , Michelle Luo[1], Frances C. Andrada[1] , Carol Kim[1] , Wanjie Sun[2] , Lingjie Zhou[2], Stella Grosser[2], Sarah Yim[1], M. Stacey Ricci[1]

[1]Office of Therapeutic Biologics and Biosimilars, Office of New Drugs, CDER, U.S. FDA
[2]Office of Biostatistics, Office of Translations Sciences, CDER, U.S. FDA

Also see FDA's summary of this research conducted by FDA staff: *Spotlight on CDER Science*: Safety Outcomes When "Switching" Between Biosimilars and Reference Products

Cavazzoni P, Yim S. The Science of Biosimilars—Updating Interchangeability. *JAMA.* Published online September 18, 2024.

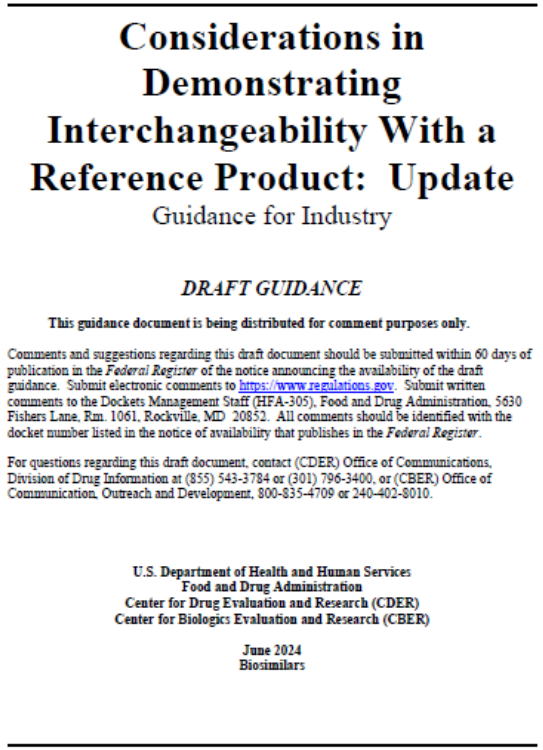
Summary of Major Results from FDA Analyses

- **5,252 patients** underwent at least one switch to or from a biosimilar and its reference biologic were identified—results compared for **5,770 patients** who were not switched
  - 28 STPs had a single switch; 16 STPs had multiple switches (3-5 switches within STP)
- **Safety data** showed an overall risk difference (95% CI) across STPs of:
  - 0.00 (-0.00, 0.00) for **deaths**,
  - 0.00 (-0.01, 0.01) for **serious adverse events**, and
  - 0.00 (-0.01, 0.00) for **treatment discontinuation**
- **Immunogenicity data** showed **similar incidence** of anti-drug antibodies and neutralizing antibodies in patients within a STP who were switched to or from a biosimilar to its reference biologic and patients who were not switched.
- **Immune related adverse events** such as anaphylaxis, hypersensitivity reactions, and injection site reactions were similar in switched and non-switched patients.

STP=Switch Treatment Period

2024 Interchangeability Draft Guidance Update

- Experience has shown that for the products approved as biosimilars to date, the risk in terms of safety or diminished efficacy is insignificant following single or multiple switches between a reference product and a biosimilar product.
- This draft guidance:
  - Outlines a revised approach where switching studies will generally not be needed
  - Provides clarity and transparency about the FDA's thinking
  - Aligns the review and approval process with existing and emerging science
- FDA has generally recommended switching studies in the past as part of the data package needed to demonstrate interchangeability of a biosimilar; however, they would all have been approved without additional clinical (switching study) data following the new guidance.
- **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.**



Considerations in Demonstrating Interchangeability With a Reference Product: Update

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Office of Communications, Division of Drug Information at (855) 543-3784 or (301) 796-3400, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

June 2024
Biosimilars

Key Takeaways about Interchangeability

- Greater understanding of immunogenicity associated with biosimilars

- Risks in terms of safety and diminished efficacy is insignificant following single or multiple switches between a reference product and a biosimilar product

- Because of the science and the Agency's evolved thinking, the interchangeability guidance has been updated

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CLINICAL RELEVANCE

Using Biosimilar and Interchangeable Products

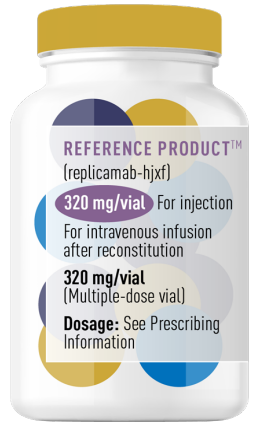
Using Reference, Biosimilar, and Interchangeable Products

- Patients and healthcare 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 healthcare provider, subject to state laws

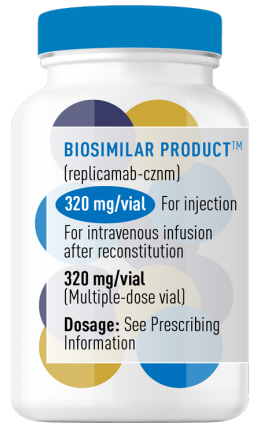
Biosimilar and Interchangeable Labeling

- The labeling summarizes the scientific information healthcare 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)
- Healthcare 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

Reference Product



Biosimilar Product



The FDA Purple Book

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).

Enter at least 3 letters

Advanced Search

Database last updated: April 22, 2025

Homepage & Simple Search

- 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).

etan

Enbrel (etanercept)	***BLA Number:*** *103795*	*351(a)*
Enbrel Mini (etanercept)	***BLA Number:*** *103795*	*351(a)*
Erelzi (etanercept-szzs)	***BLA Number:*** *761042*	*351(k) Biosimilar*
Erelzi Sensoready (etanercept-szzs)	***BLA Number:*** *761042*	*351(k) Biosimilar*
Eticovo (etanercept-ykro)	***BLA Number:*** *761066*	*351(k) Biosimilar*

Advanced Search

Database last updated: April 22, 2025

Simple Search Results

Proprietary Name
Erelzi
Erelzi Sensoready

Proper Name
etanercept-szzs

PRODUCT LABEL

Drugs@FDA: FDA-Approved Drugs

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Biologic License Application (BLA): 761042
Company: SANDOZ

- Medication Guide
- Summary Review

Products on BLA 761042

CSV | Excel | Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD
ERELZI	ETANERCEPT-SZZS	25MG/0.5ML	INJECTABLE; INJECTION	Prescription	None	No
ERELZI	ETANERCEPT-SZZS	50MG/ML	INJECTABLE; INJECTION	Prescription	None	No

Showing 1 to 2 of 2 entries

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

Labels for BLA 761042

Purple Book
Database of Licensed Biological Products

Purple Book Homepage
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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)

Proprietary Name
Eticovo
Proper Name
etanercept-ykro
PRODUCT LABEL

Reference Product(s)

Proprietary Name
Enbrel
Enbrel Mini
Proper Name
etanercept
PRODUCT LABEL

Product Details

Purple Book
Database of Licensed Biological Products

- Purple Book Homepage
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- 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	Marketing Status
001	Injection	Subcutaneous	25MG/0.5ML	Pre-Filled Syringe	351(k) Biosimilar	Erelzi	Disc
002	Injection	Subcutaneous	50MG/ML	Pre-Filled Syringe	351(k) Biosimilar	Erelzi	Disc
003	Injection	Subcutaneous	50MG/ML	Autoinjector	351(k) Biosimilar	Erelzi Sensoready	Disc
004	For Injection	Subcutaneous	25MG	Multi-Dose Vial	351(k) Biosimilar	Erelzi	Disc

Proper Name
etanercept-szzs

Reference Product Proper Name
etanercept

Reference Product Proprietary Name
Enbrel

BLA Number
761042

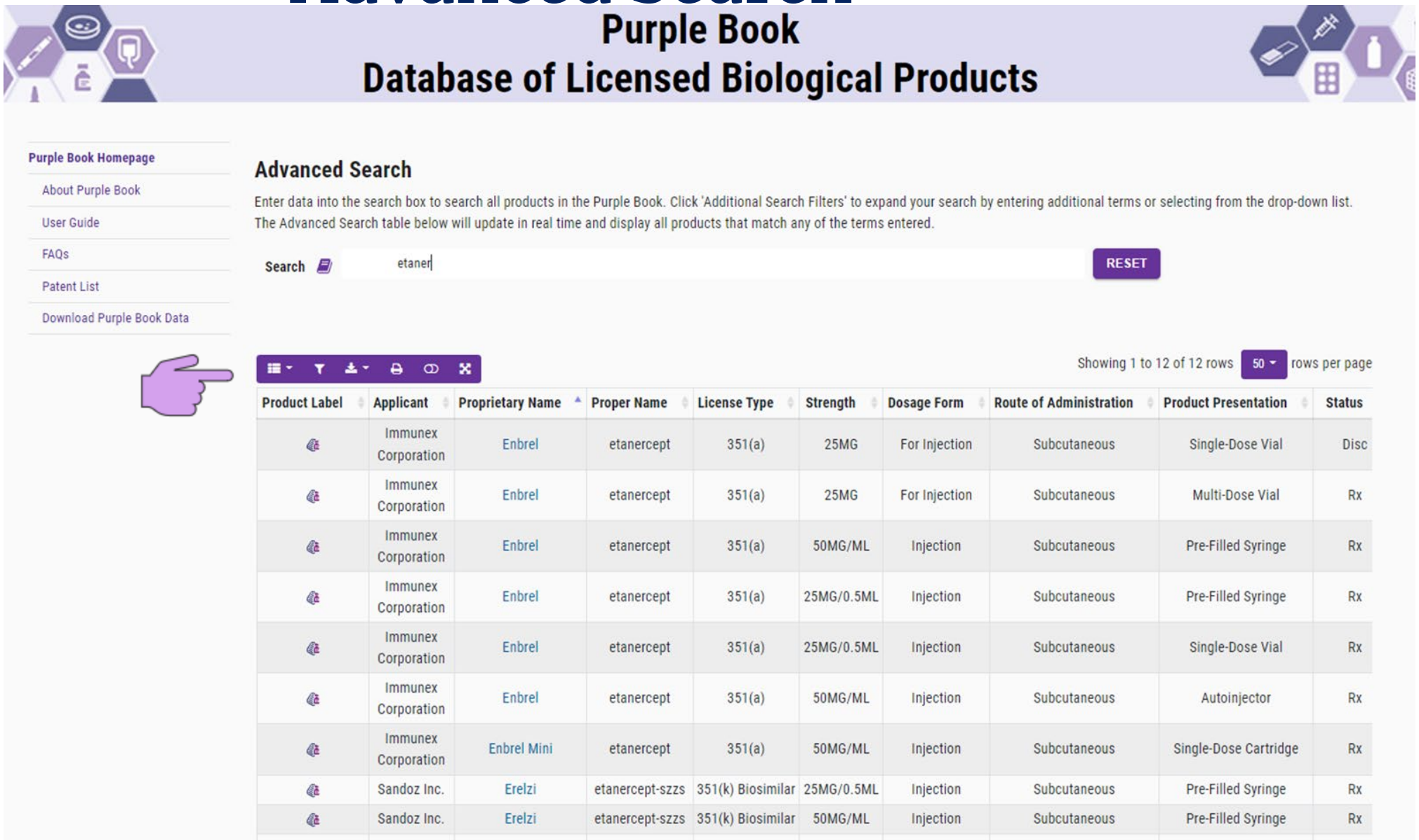
Applicant
Sandoz Inc.

Original Approval Date
August 30, 2016

Date of First Licensure

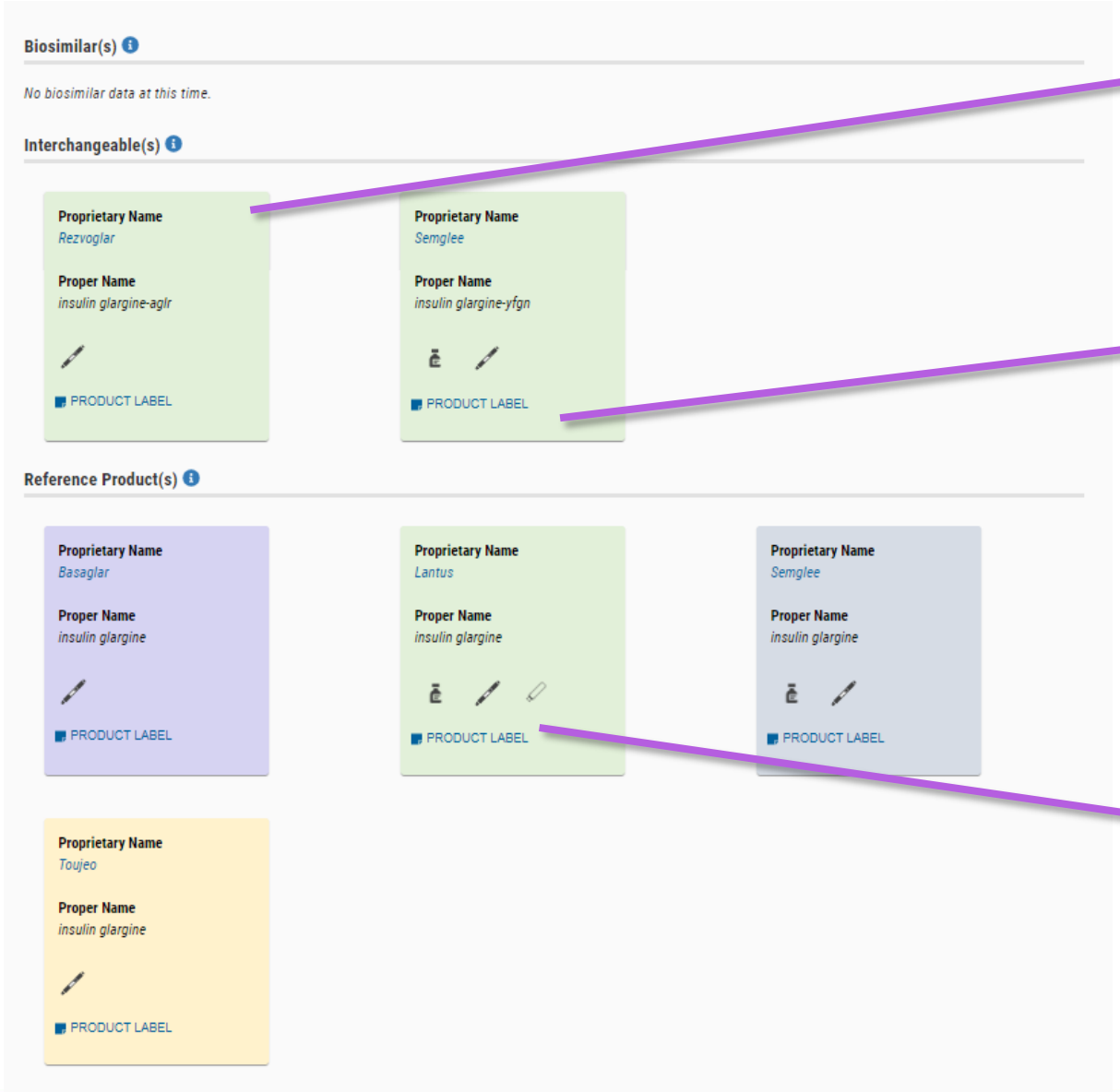
< RETURN TO SEARCH RESULTS

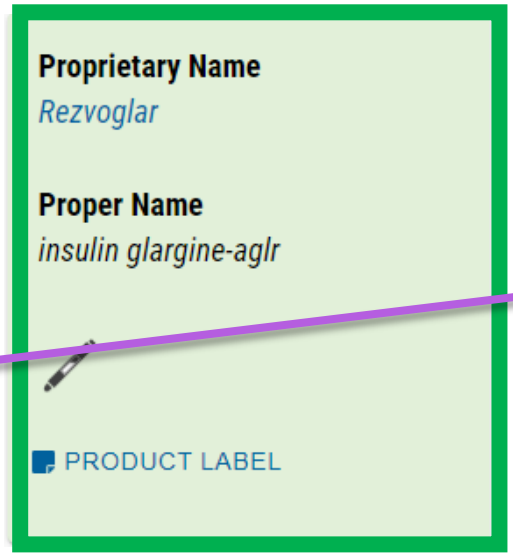
Advanced Search



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

Interchangeable Products





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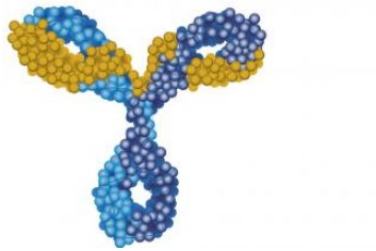
Center for Drug Evaluation and Research

fda.gov/biosimilars

Resources for Patients and Healthcare Providers

Biosimilar Education Resources



Overview for Health Care Professionals

Learn about biologics, including biosimilars and interchangeables

Review and Approval

Review and approval for biosimilars and interchangeables

Basics for Patients

Curriculum Materials for Health Care Programs

Product Information

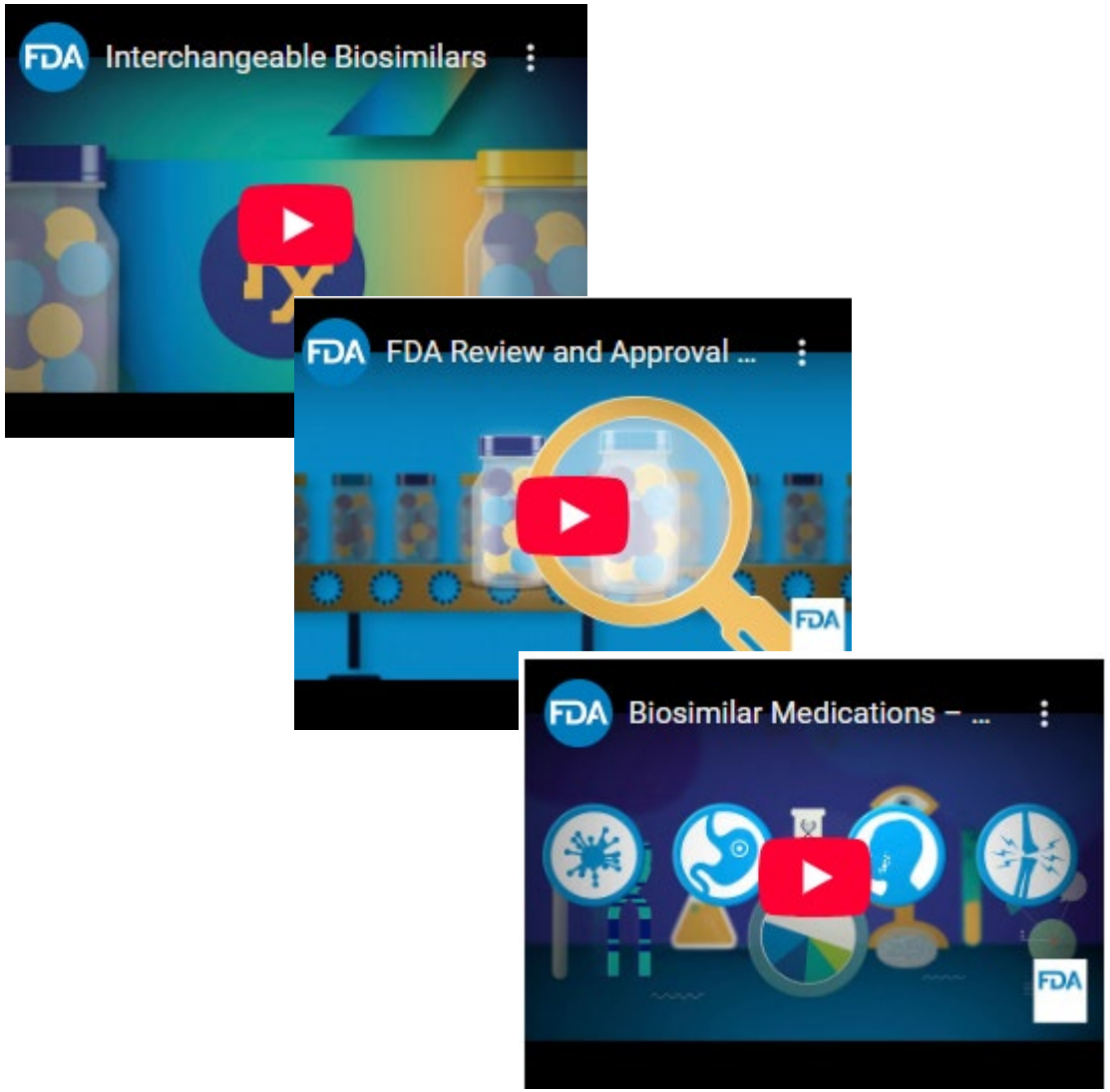
Information about FDA-approved biosimilar products

Multimedia Education Materials

Explore materials to help promote understanding of biosimilars

For more information, visit: www.fda/gov/biosimilars

Health Care Provider Materials



Biosimilar Education Resources: CME

110,493
TOTAL LEARNERS

26,672
TOTAL MD LEARNERS

81,665
TOTAL OTHER HCP LEARNERS

49,540
TOTAL TEST TAKERS

MD Learner Specialties

3,104	Dermatologists
404	Diabetologists & Endocrinologists
1,126	Hem/Onc Specialists
545	Neurologists
1,634	Ophthalmologists
3,240	Rheumatologists
577	Obstetricians & Gynecologists
2,215	Gastroenterologists
113	Nephrologists
10,147	Primary Care Physicians
3,567	Other Physicians

Top Other MD Specialties

396	Cardiologists
343	Plastic Surgery & Aesthetic Medicine
334	Orthopaedists & Orthopaedic Surgeons
301	Anesthesiologists
285	Psychiatrists

Biosimilar Education Resources: CME, continued

- The Road to Biosimilars in Rare Hematologic Conditions
- Biosimilars in Rheumatology: Building Certainty and Reducing Reluctance
- Biosimilars in Multiple Sclerosis: Are We Ready?
- Overcoming Reluctance and Enhancing Biosimilar Adoption
- Biosimilars for the Management of Eye Conditions
- Developing a Plan of Care That Includes Biosimilars When Uncertainty Is Present
- Biosimilars 102: Interchangeability, Extrapolation, and Immunogenicity -- A Regulatory Process Primer
- 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

Curriculum for Healthcare Professional Programs

- The Biosimilar Curriculum Toolkit contains multiple types of materials to help faculty integrate biosimilars and interchangeable products into the education and professional training of healthcare students.

- Goal is to increase knowledge and real-world application of concepts among students in healthcare degree programs (Medicine, Nursing, Physician Associate/ Assistant, and Pharmacy).

- Materials are designed to meet a variety of needs and are divided into 2 levels of content.

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

Curriculum for Healthcare Professional Programs, continued

- Materials include a teaching guide, slide decks, videos, information sheets, case studies, discussion questions, exercises, and more.

- Topics covered include:
  - Biologics, Biosimilars and Interchangeability
  - Approval pathways for biological products
  - Manufacturing and variation in biological products
  - Comparative Analytical Assessment
  - Labeling and prescribing of biosimilar and interchangeable biosimilar products

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

Resources/References

Herndon, T. M., Ausín, C., Brahme, N. N., Schrieber, S. J., Luo, M., Andrada, F., Kim, C. H., Sun, W., Zhou, L., Grosser, S., Yim, S., & Ricci, M. (2023). Safety outcomes when switching between biosimilars and reference biologics: A systematic review and meta-analysis. *PLOS ONE*, *18*(10), e0292231–e0292231. https://doi.org/10.1371/journal.pone.0292231

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THANK YOU

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

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Questions?

How to Obtain CE/CME Credits

2025 JUNE CCSS: Evidence-Based Approaches for Advancing Excellence in Primary Care

Credits are awarded by session. To claim CE/CME credit or certificate of attendance for the session(s) you attend, you must register by 4:00 p.m. ET on June 6, and then you must complete the course evaluation and posttest for each session by 11:59 p.m. ET on Thursday, June 19, 2025.

1. Visit the main event page at https://www.dhaj7-cepo.com/content/2025-jun-ccss to register for the live event or to log in to your account if already registered.
2. On the main event page, select the "Get Started" tab (located in the menu below the event title on the desktop and at the bottom of the page on mobile devices). Note: This tab will not appear unless you are registered and logged in to your account.
3. Under the "Get Started" tab, scroll down to a session you attended and select "Claim credit."
4. Proceed to take the evaluation and posttest to obtain your certificate after the session has ended.

All completed courses and certificates are available in your account. Refer to your Pending Activities for sessions you have yet to complete. You must complete the required course items by Thursday, June 19 to receive credit.

Questions? Email DHA, J-7, CEPO at dha.ncr.j7.mbx.cepo-cms-support@health.mil.