FDA Drug Topics:

Biosimilar and Interchangeable Biosimilars: Review of Scientific Concepts, Case Studies, and Resources

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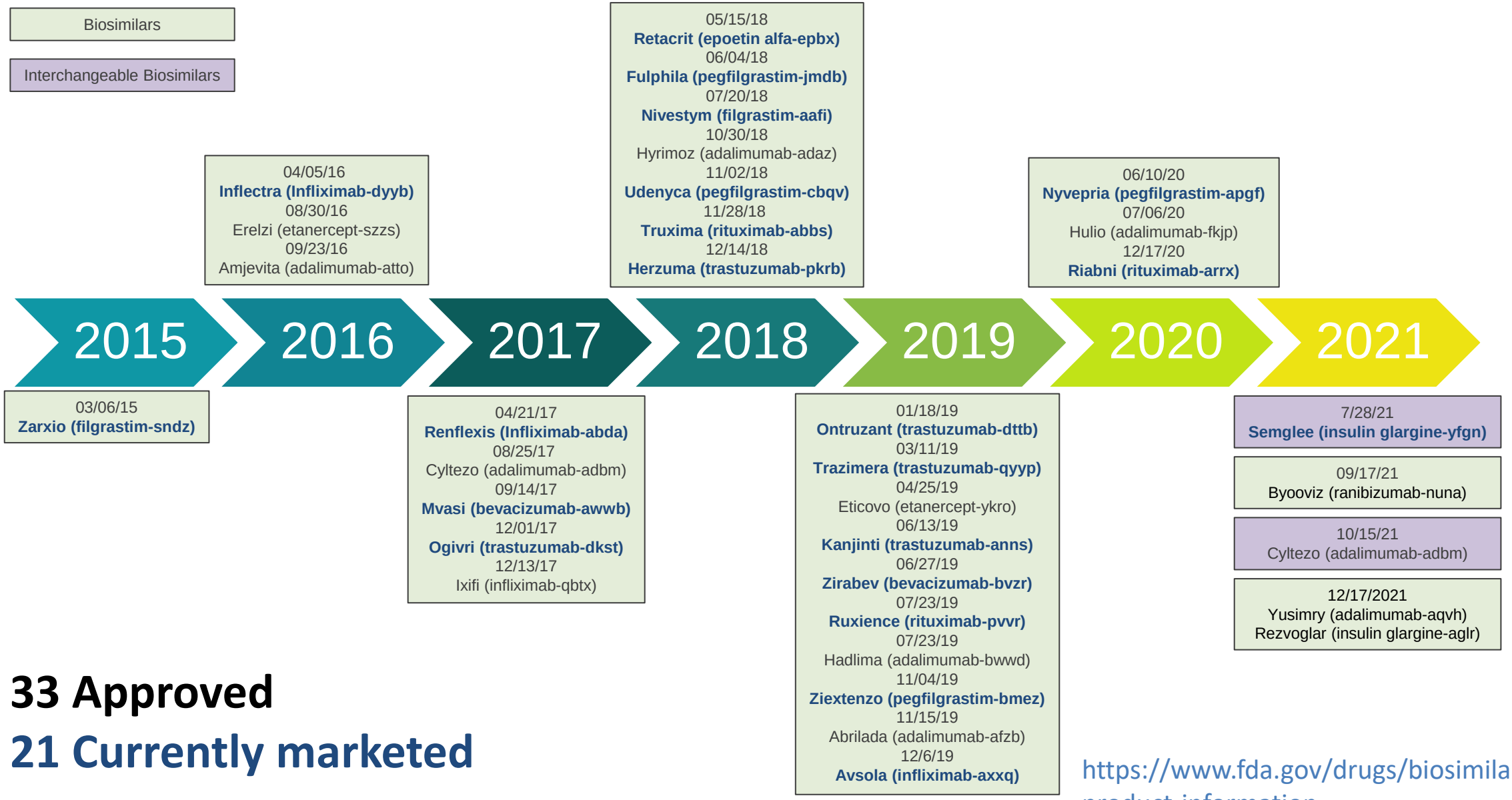
Timeline of Biosimilar and Interchangeable Biosimilar Approvals

Biosimilars

Interchangeable Biosimilars



33 Approved

21 Currently marketed

https://www.fda.gov/drugs/biosimilars/biosimilar-product-information

Learning Objectives

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. Differentiate between the requirements for FDA approval of generics and biosimilars/interchangeables and discuss the availability of insulin products.
4. Review case studies of approved biosimilar and interchangeable products.
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.

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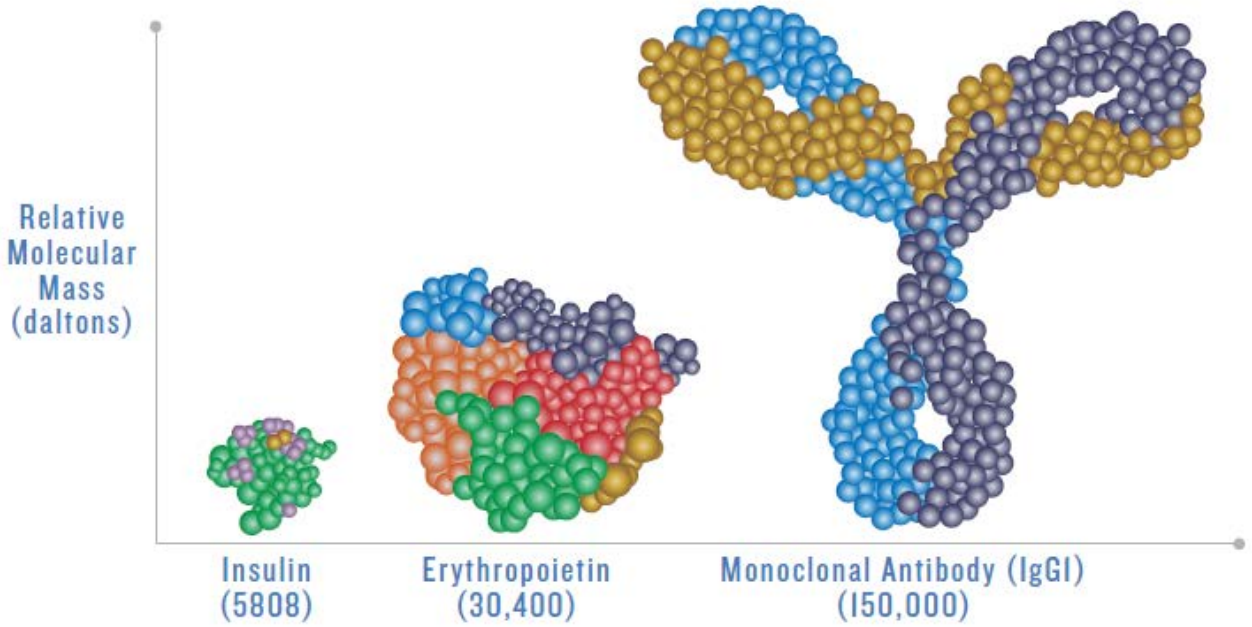
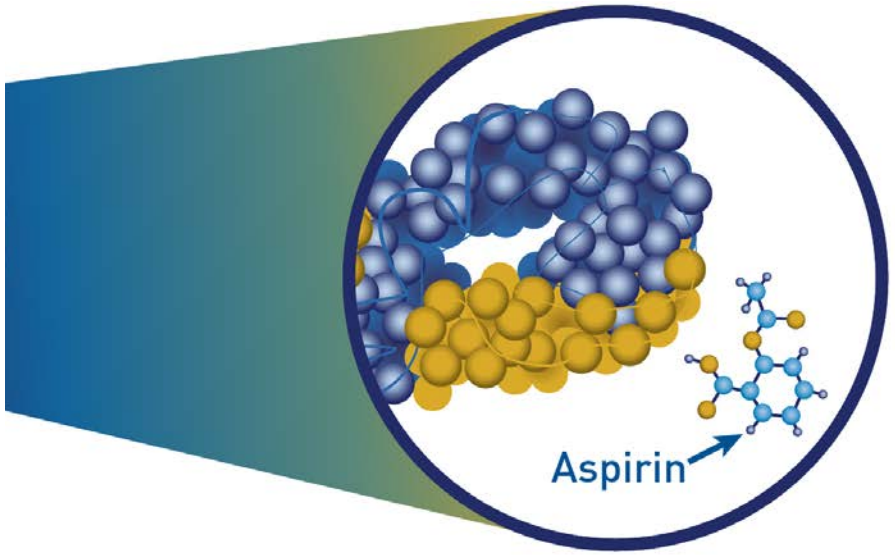
Biosimilar and Interchangeable Products: Scientific Concepts and Regulatory Framework

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

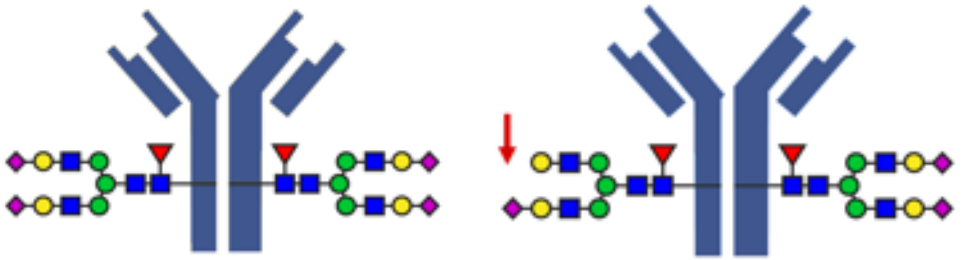




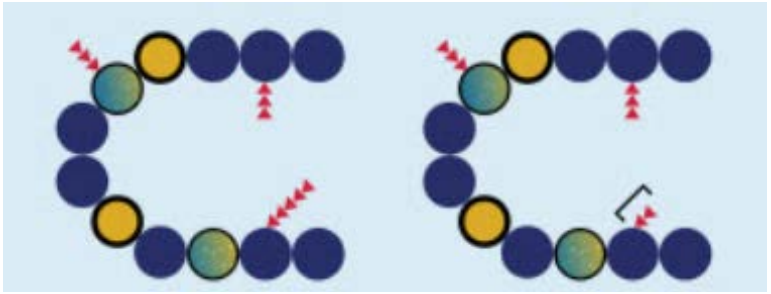
Modified from Mellstedt H, EJC Supplements II, 2013, 3, I - II

Therapeutic Proteins: Complexity

- Cells can make exact copies of a protein 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)

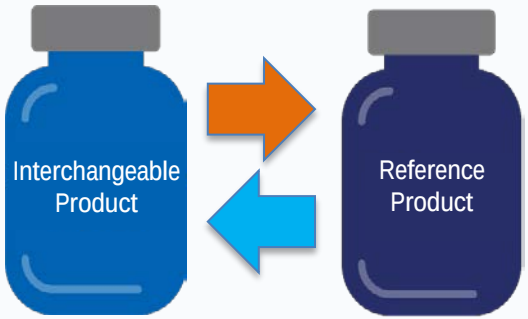
Key Definitions from the BPCI Act

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

General Requirements

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

- Is **biosimilar** to a 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.

General Requirements, cont.

A biosimilar is highly similar to a reference product

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

Purity

Molecular structure

Bioactivity

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

A biosimilar has no clinically meaningful differences from a reference product

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

Pharmacokinetic and, if needed, pharmacodynamic studies

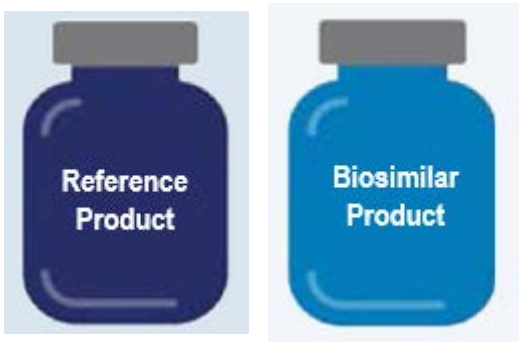
Immunogenicity assessment

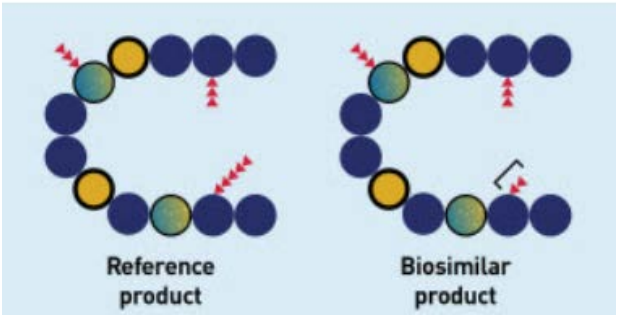
Additional clinical studies as needed

Studies may be done independently or combined.

Can Most Biologics be Copied Exactly? No

- Most biologics are mixtures of variants
- Using advanced scientific analysis, molecular patterns and profiles emerge
- Biosimilars try to match the patterns and variations of the reference product
- Both the reference product (RP) and biosimilar (BS) contain these variants and develop manufacturing processes to keep a consistent mix





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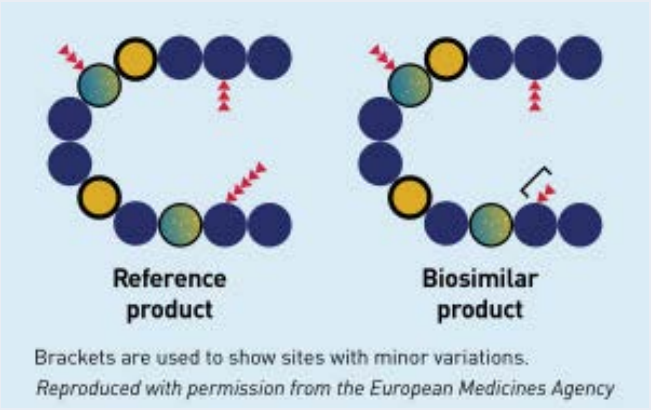
FDA's Recommended Approach to the Development of Biosimilars and Interchangeable Biosimilars

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

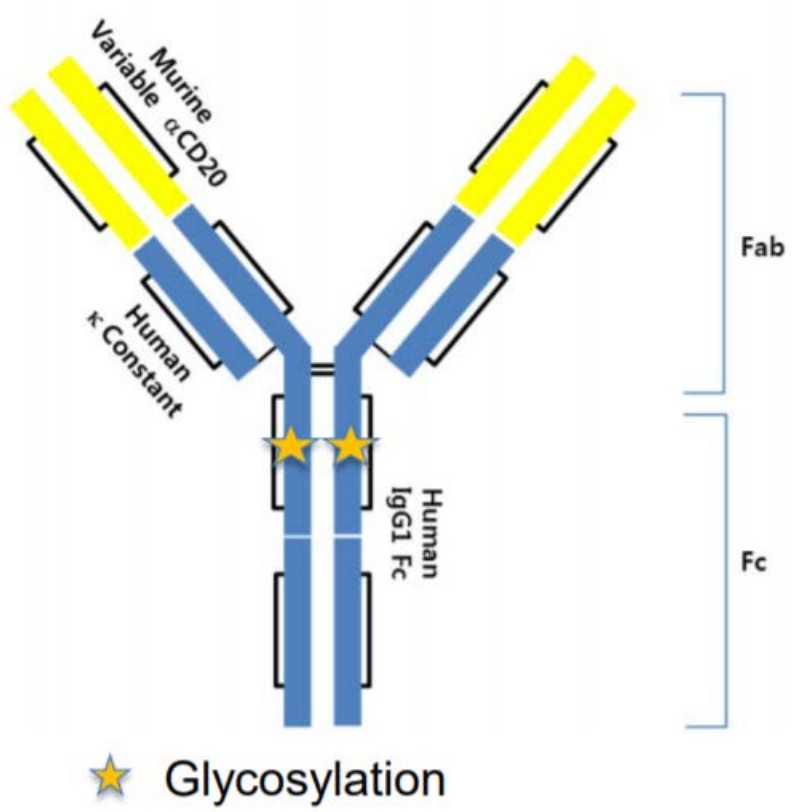
	Generic (Orange Book)	Biosimilar (Purple Book)
Assessment	Same Active Ingredient PK Bioequivalence	Highly Similar No Clinically Meaningful Differences
Example schematic of product comparisons. Comparative Analytical data expected for both products	 **Reference Listed Drug** = **Generic Drug**	 **Reference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

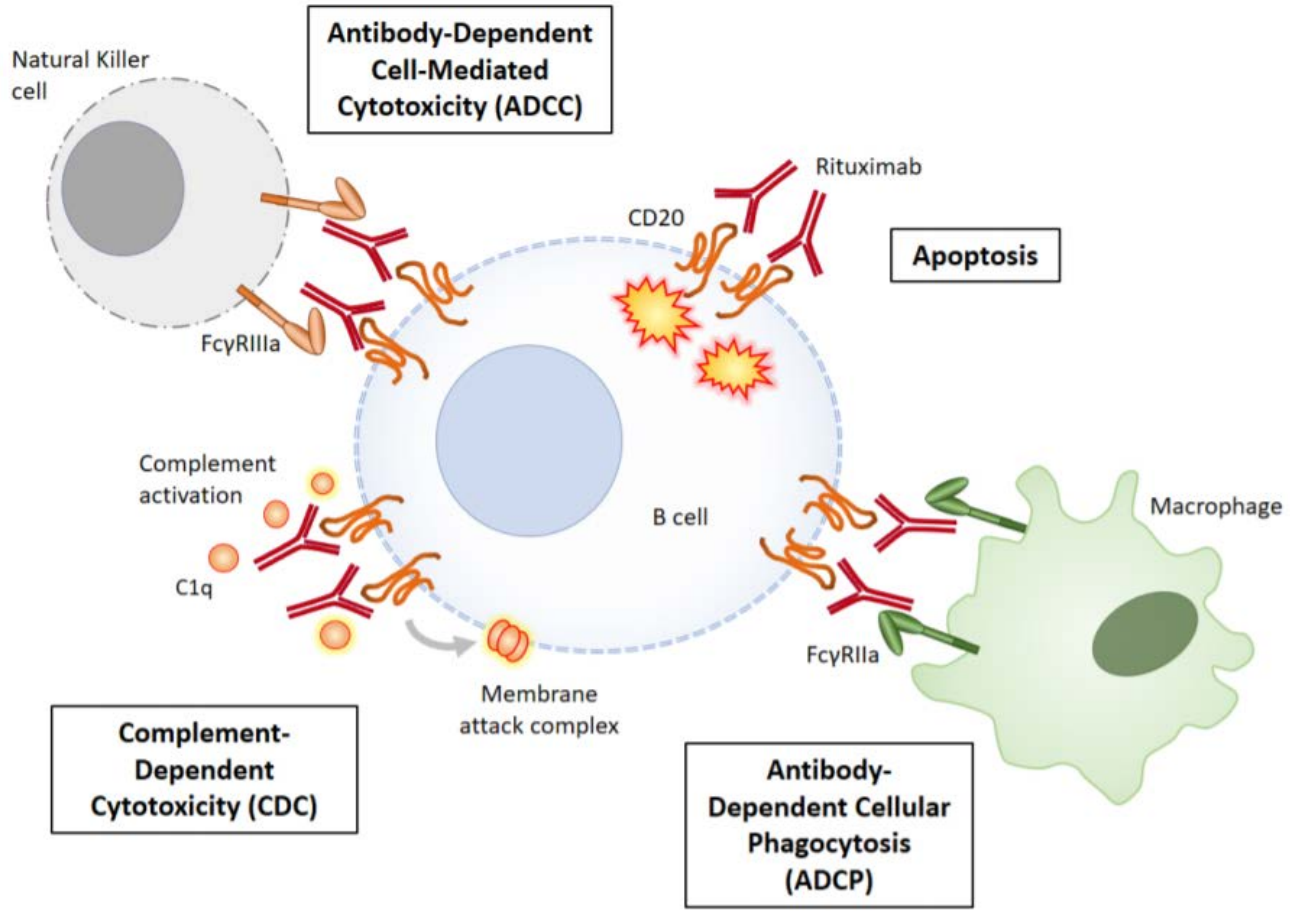
Both are "abbreviated" development pathways that have distinct statutory requirements and comparative studies supporting their approval.

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

Case study of Data Used to Support Biosimilarity





CT-P10, proposed biosimilar to US-Rituximab

Adapted from 10/10/18 FDA Oncology Drugs Advisory Committee (ODAC) Slides

Case study of Analytical Data Used to Support Biosimilarity

Quality Attributes Evaluated

Primary structure

- Intact molecular weight
- Amino acid sequence
- Extinction coefficient

Higher order structure

- Secondary structure
- Tertiary structure
- Thermal stability
- Disulfide bonds

Glycosylation

- Afucosylation
- Galactosylation
- High Mannose content
- Sialylation

Biological activity

- CDC
- ADCC
- ADCP
- Apoptosis

- CD20 binding
- C1q binding
- FcγRIIIa V type binding
- FcγRIIIa F type binding
- FcγRIIIb binding
- FcγRIIa binding
- FcγRIIb binding
- FcγRI binding
- FcRn binding

Protein Concentration

- Concentration in mass per volume

Size Variants

- Monomer, dimer, high and low molecular weight species
- Intact IgG, “non-assembled forms” of heavy chain and light chain, fragments

Charge Variants

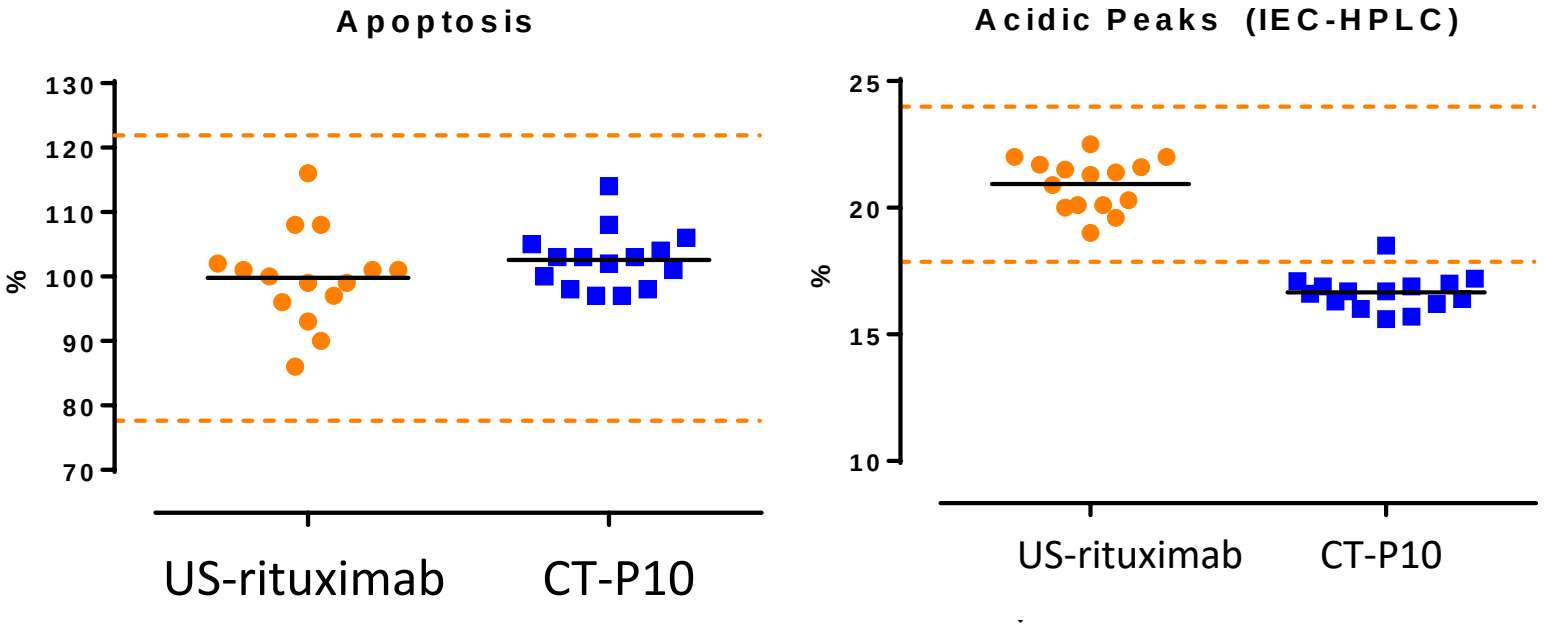
- Acidic, main, basic species

Post-translational Modifications

- Deamidation, Oxidation, Glycation, N- and C-terminal variants

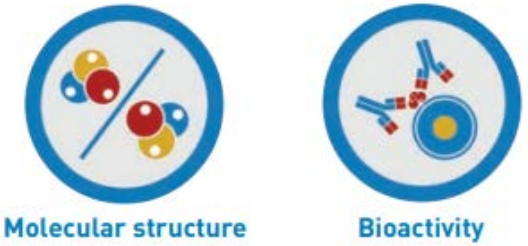
Adapted from Oct. 10, 18 FDA ODAC Slides: Slides from the October 10, 2018 Meeting of the Oncologic Drugs Advisory Committee

Case study CT-P10 vs. US-rituximab Potency and Charge Variants



Additional Analytical Studies Showed:

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



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

Adapted from Oct. 10, 18 FDA ODAC Slides: Slides from the October 10, 2018 Meeting of the Oncologic Drugs Advisory Committee

Case study – Overall Conclusions From the Comparative Analytical Assessment

- The comparative analytical data demonstrate that CT-P10 is highly similar to US-rituximab notwithstanding minor differences in clinically inactive components.

- The analytical results add to the totality of the evidence to support a demonstration of biosimilarity between CT-P10 and US-rituximab.

Adapted from 10/10/18 FDA ODAC Slides

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

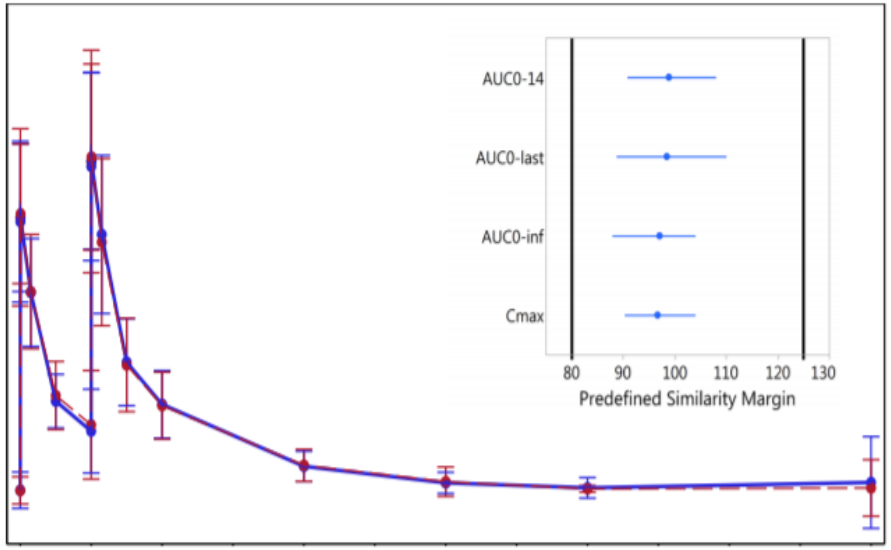
Type of Clinical Data

- Clinical Pharmacology Studies
  - **PK and/or PD** is generally considered more sensitive than clinical efficacy endpoints when **assessing for differences between products**, should they exist
  - **PK and PD similarity** data support 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** is considered necessary if there are **residual uncertainties** about whether there are **clinically meaningful differences** between the proposed product and reference product based on structural and functional characterization, animal testing, human PK and PD data, and clinical immunogenicity assessment.

Case Example CT-P10 vs. US-Rituximab Clinical Program

Similar Exposure **Similar Efficacy** **Similar Safety**

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



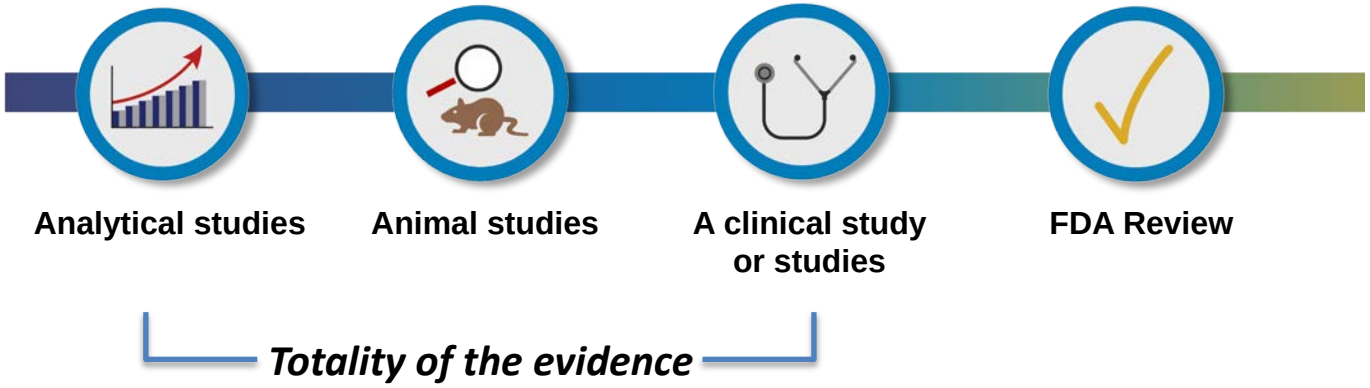
Comparative Clinical Study in patients with low tumor burden follicular lymphoma (LTBFL) for comparing efficacy, safety, and immunogenicity

	CT-P10	US-rituximab
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	

Adapted from Oct. 10, 18 FDA ODAC Slides: Slides from the October 10, 2018 Meeting of the Oncologic Drugs Advisory Committee

Case Study - Summary

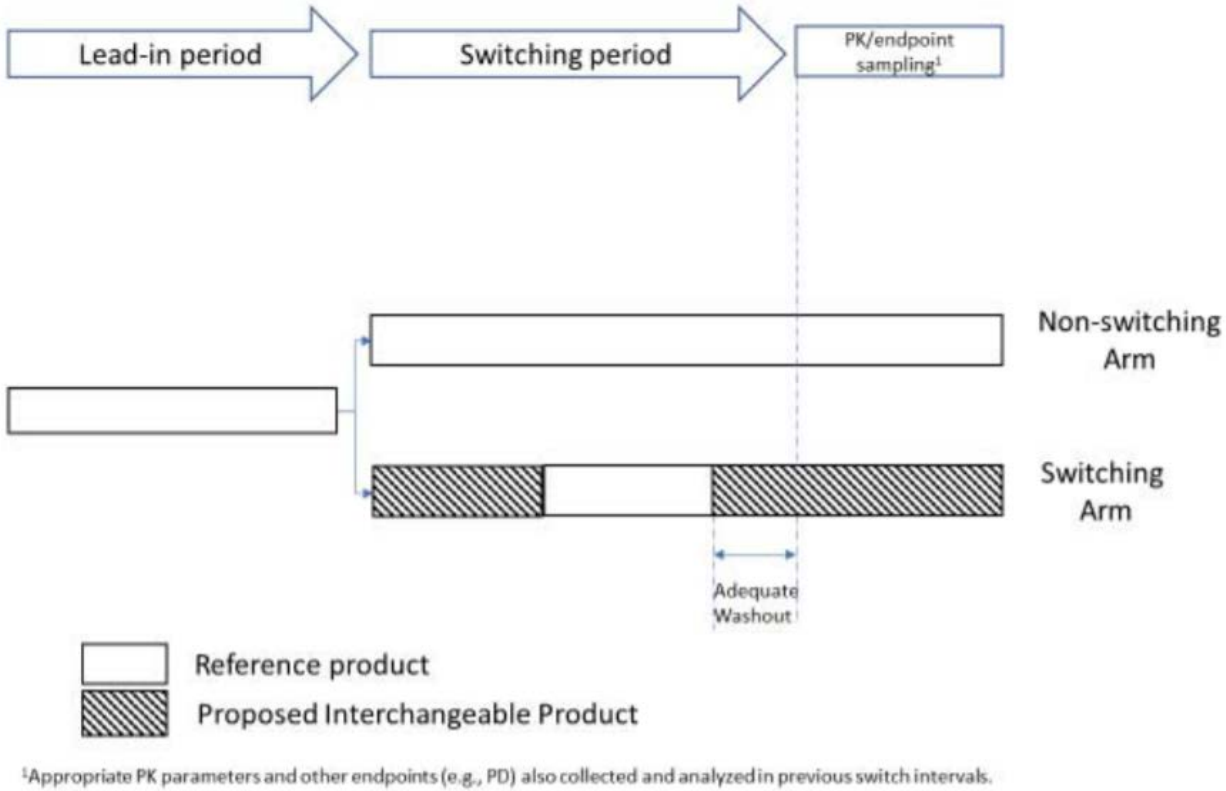
- Comparative analytical data demonstrate that CT-P10 and US-rituximab are highly similar, notwithstanding minor differences in clinically inactive components
- PK and immunogenicity data in patients with RA support the demonstration of no clinically meaningful differences
- Clinical data obtained in patients with LTBFL support a demonstration that there are no clinically meaningful differences between CT-P10 and US-rituximab
- The totality of the data support the Applicant's claim that CT-P10 is biosimilar to US-licensed rituximab



Adapted from 10/10/18 FDA ODAC Slides

Interchangeable Product Examples

- The extent of additional data, including clinical data needed to support a demonstration of interchangeability will depend on factors, such as the product's complexity or a product's specific immunogenicity risk.



Adalimumab-adbm

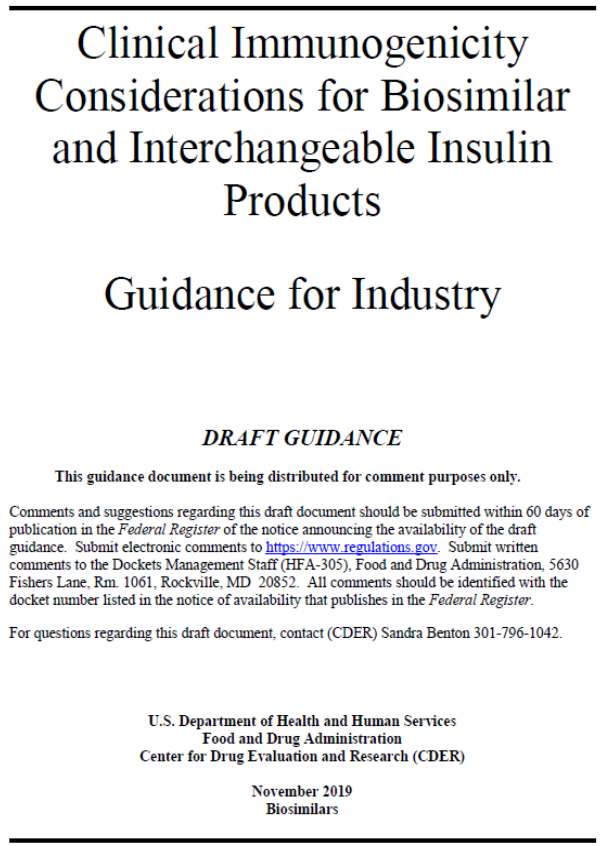
- Adalimumab-adbm previously approved as biosimilar to US-adalimumab
- Switching study designed as recommend in guidance*

*Considerations in Demonstrating Interchangeability With a Reference Product Guidance for Industry | FDA

Interchangeable Product Examples, cont.

Insulin glargine-yfgn

- Comparative analytical assessment to support “highly similar” conclusion
- Clinical pharmacology PK/PD similarity study
- Immunogenicity assessment justification submitted, per guidance*



Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products

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) Sandra Benton 301-796-1042.

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

November 2019
Biosimilars

Switching study was determined to be unnecessary

- **Relatively small, structurally uncomplicated, well characterized**
- **Minimal or no risk of clinical impact from immunogenicity**

*Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products | FDA

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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.

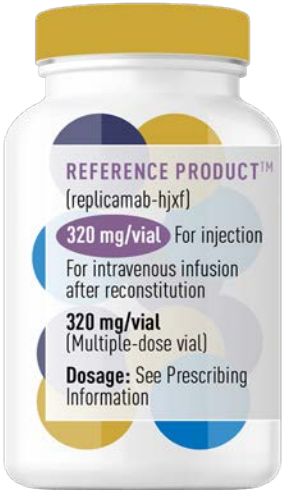
- Biosimilar and interchangeable biosimilar products can be used in patients who have previously been treated with the reference product (i.e., treatment-experienced), and in patients who have not previously been treated with the reference product (i.e., treatment-naïve).

- Interchangeable biosimilars may be substituted for the reference product without the intervention of the prescribing health care provider, subject to state laws.

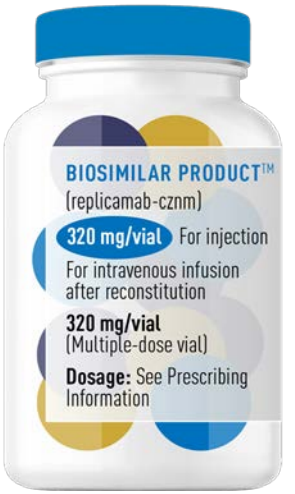
Biosimilar and Interchangeable Labeling

- 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).
- 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" or an "Interchangeability Statement" describing the product's relationship to its reference product.

Reference Product



Biosimilar Product



Biosimilarity Statement

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)

Limitations of Use
Text (1)

----------DOSAGE AND ADMINISTRATION----------

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

----------DOSAGE FORMS AND STRENGTHS----------

Dosage form(s): strength(s) (3)

----------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)

*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 as 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's high standards for approval means healthcare professionals and patients can be confident in the safety and effectiveness of biosimilar and interchangeable products.

Fact: FDA's approval of an interchangeable biosimilar does not indicate a higher standard of biosimilarity, 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.

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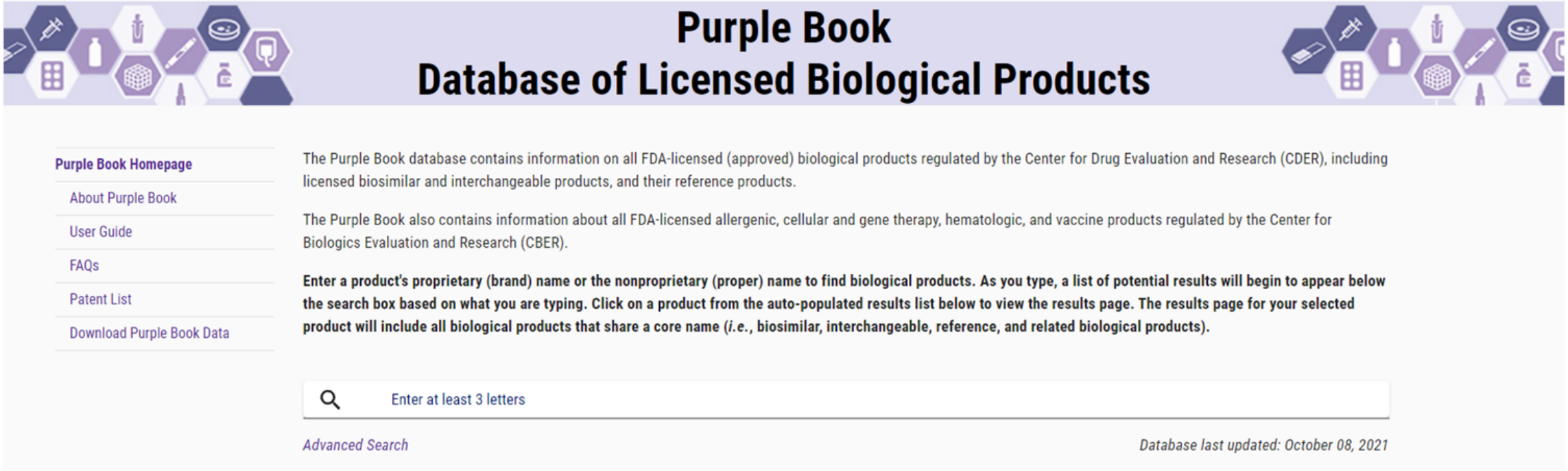
Resources for Health Care Providers

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



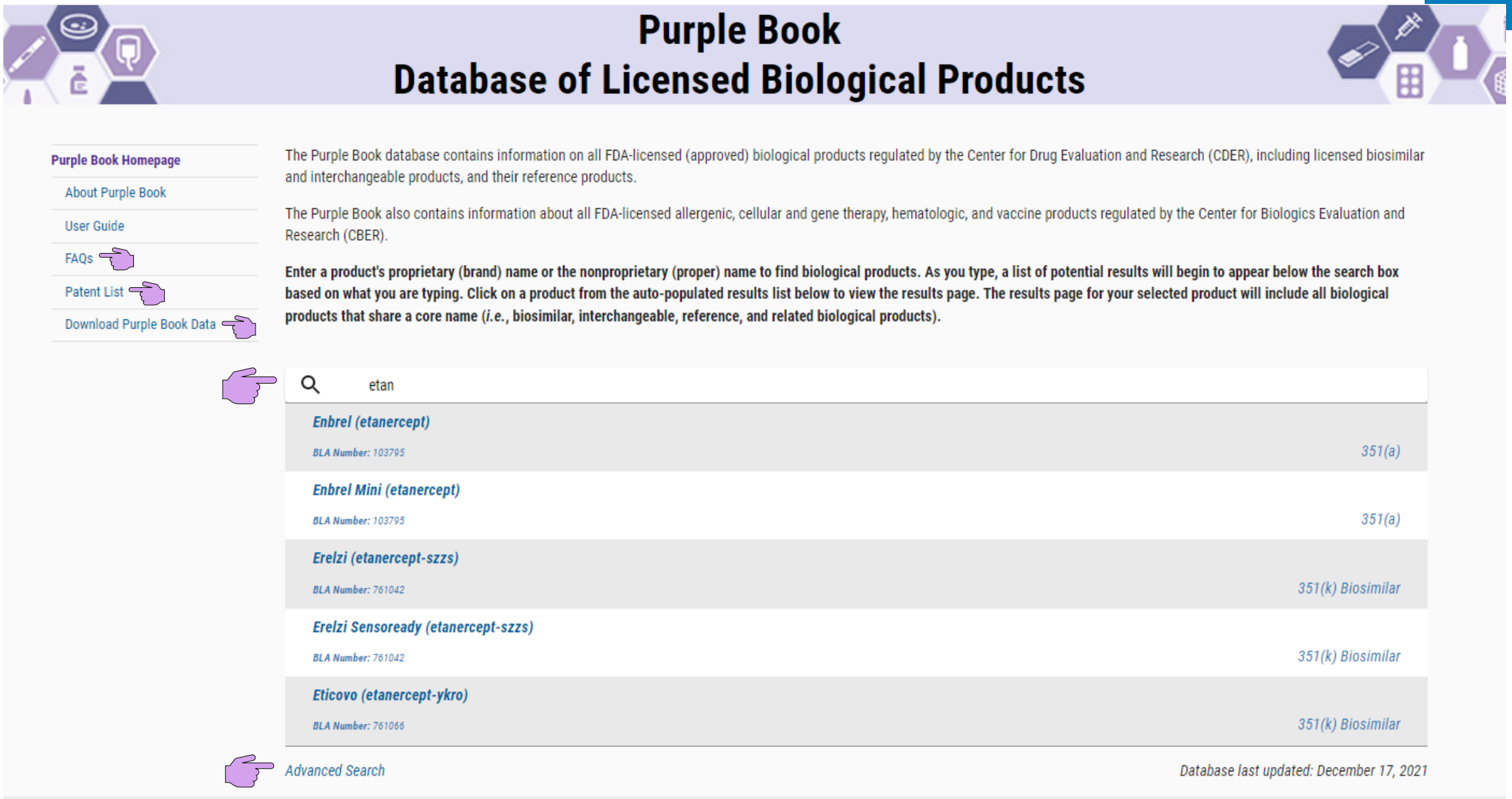
Purple Book's Features

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.

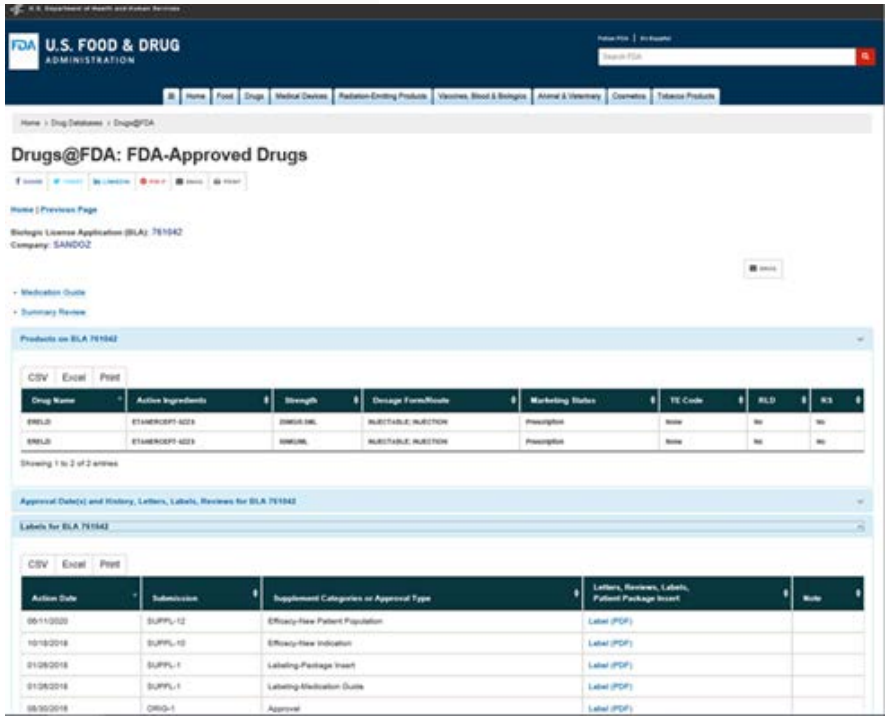
Features tailored to different user needs, including:

- 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



Simple Search Results



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.

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-szzs

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

< RETURN TO SEARCH RESULTS

Advanced Search

Purple Book
Database of Licensed Biological Products

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

Advanced Search

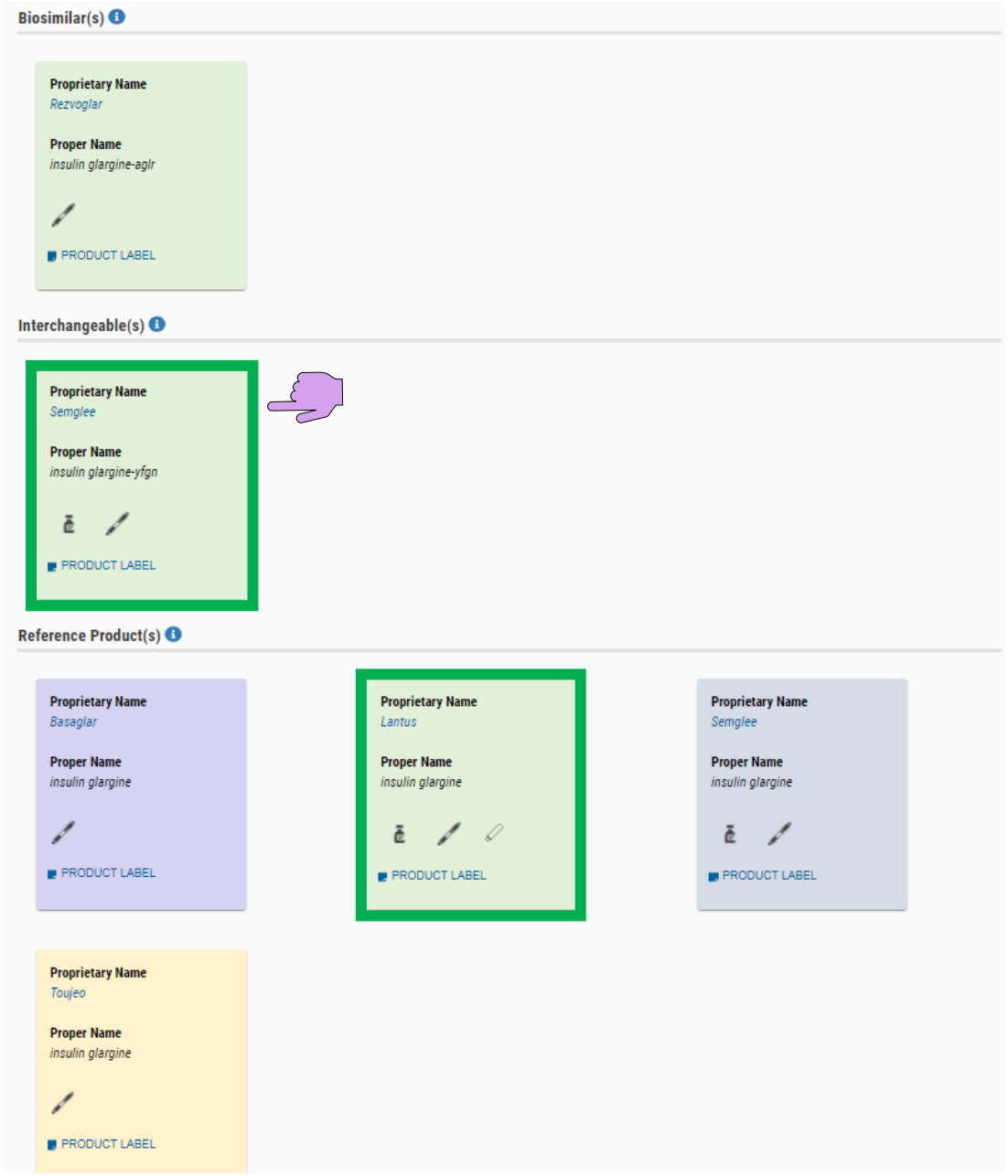
Enter data into the search box to search all products in the Purple Book. Click 'Additional Search Filters' to expand your search by entering additional terms or selecting from the drop-down list. The Advanced Search table below will update in real time and display all products that match any of the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

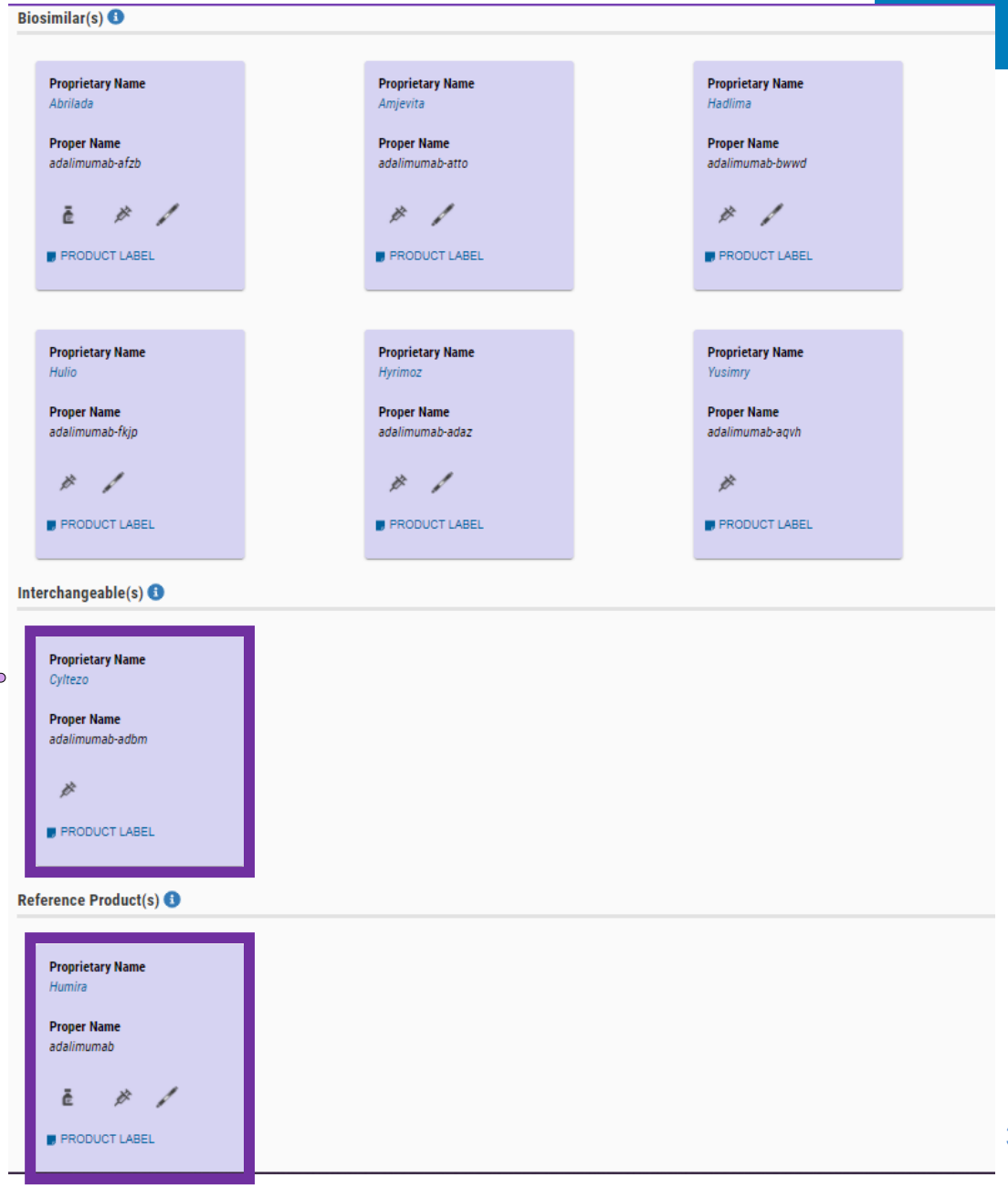
Search etaner RESET

Showing 1 to 12 of 12 rows 50 rows per page

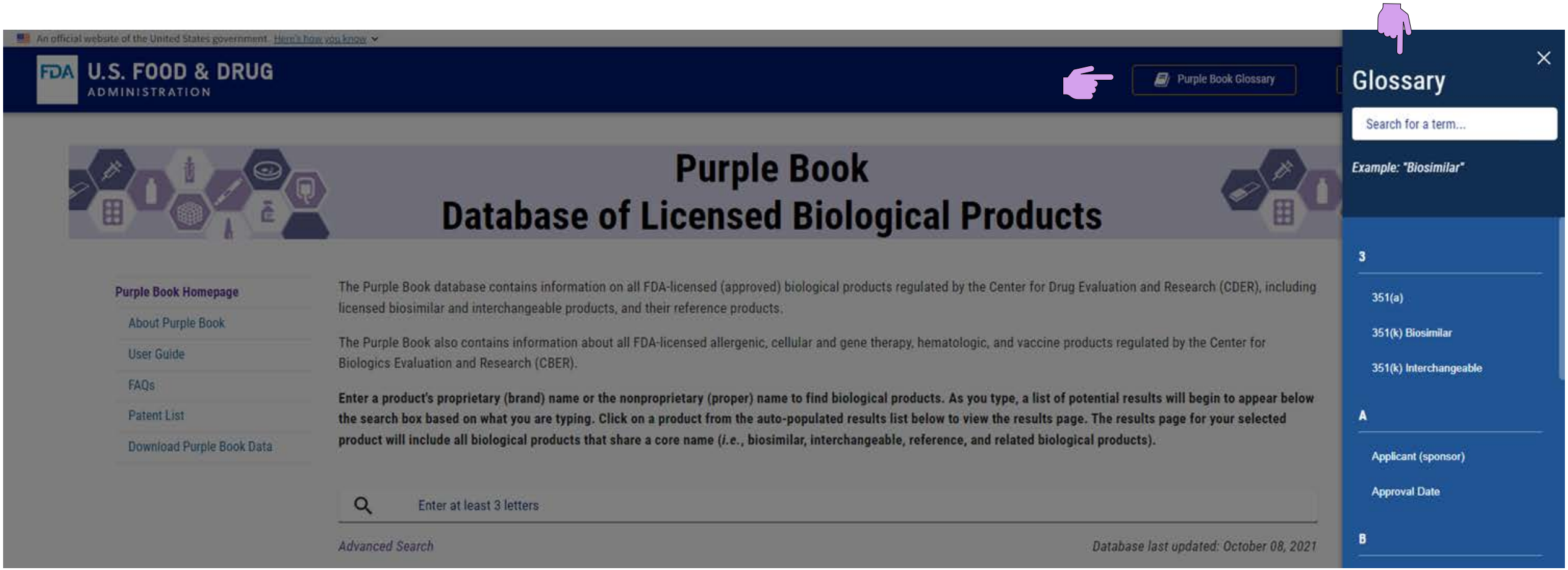
Product Label	Applicant	Proprietary Name	Proper Name	License Type	Strength	Dosage Form	Route of Administration	Product Presentation	Status
	Immunex Corporation	Enbrel	etanercept	351(a)	25MG	For Injection	Subcutaneous	Single-Dose Vial	Disc
	Immunex Corporation	Enbrel	etanercept	351(a)	25MG	For Injection	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-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





Glossary of Terms

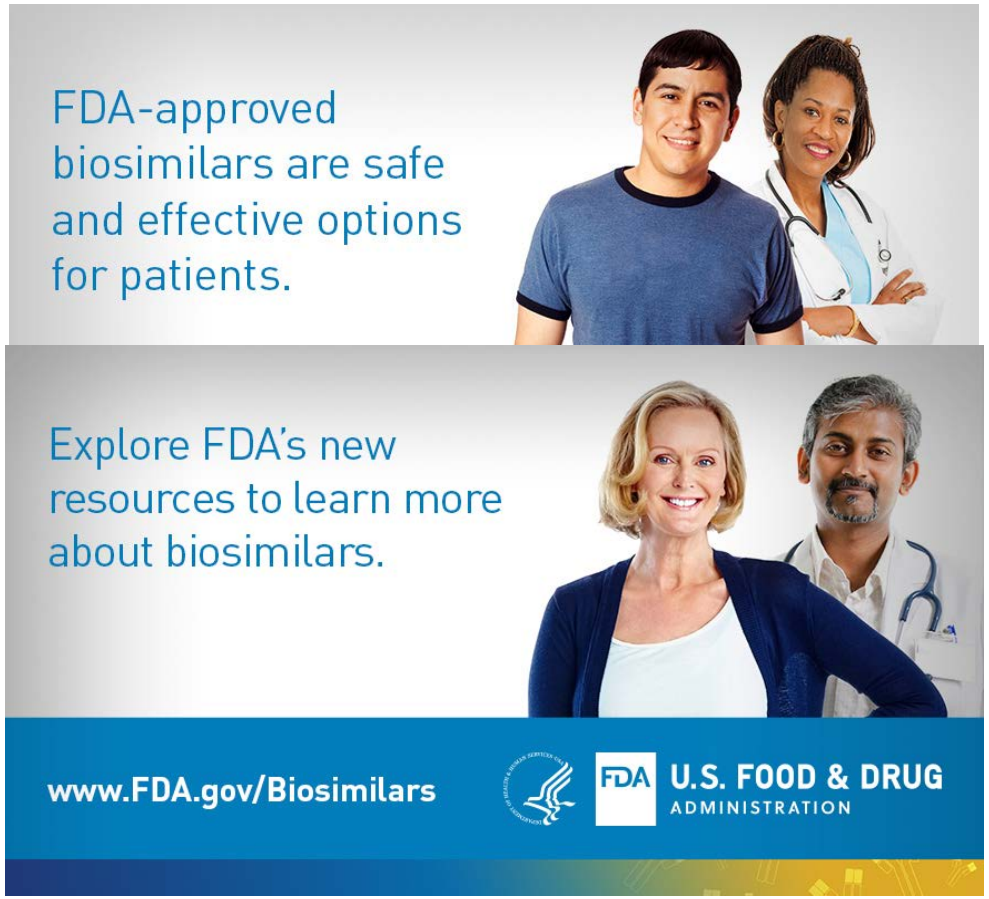


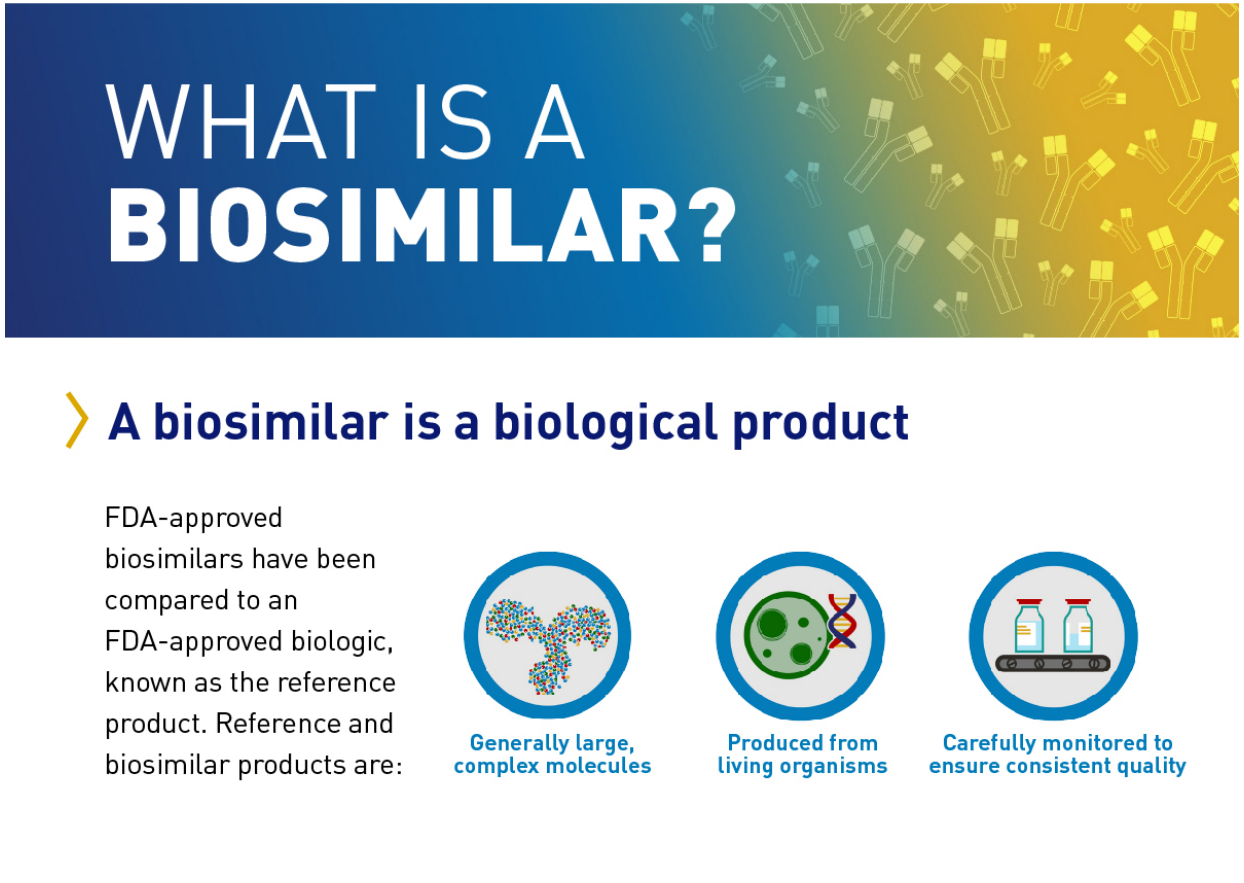
Education and Outreach

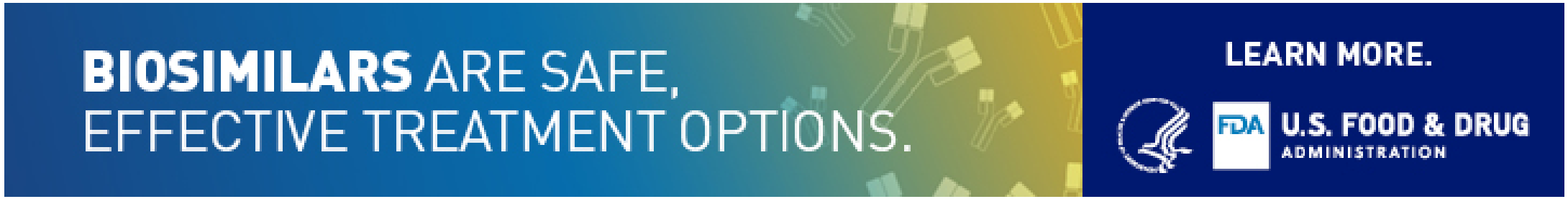
- FDA is committed to developing effective communications to improve understanding of biosimilars among patients, health care providers and payors
  - **Engaging** with health care professional and patient stakeholders
  - **Developing** educational materials for health care prescribers, pharmacists,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

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

Health Care Provider Materials







Curriculum for Health Care Degree Programs

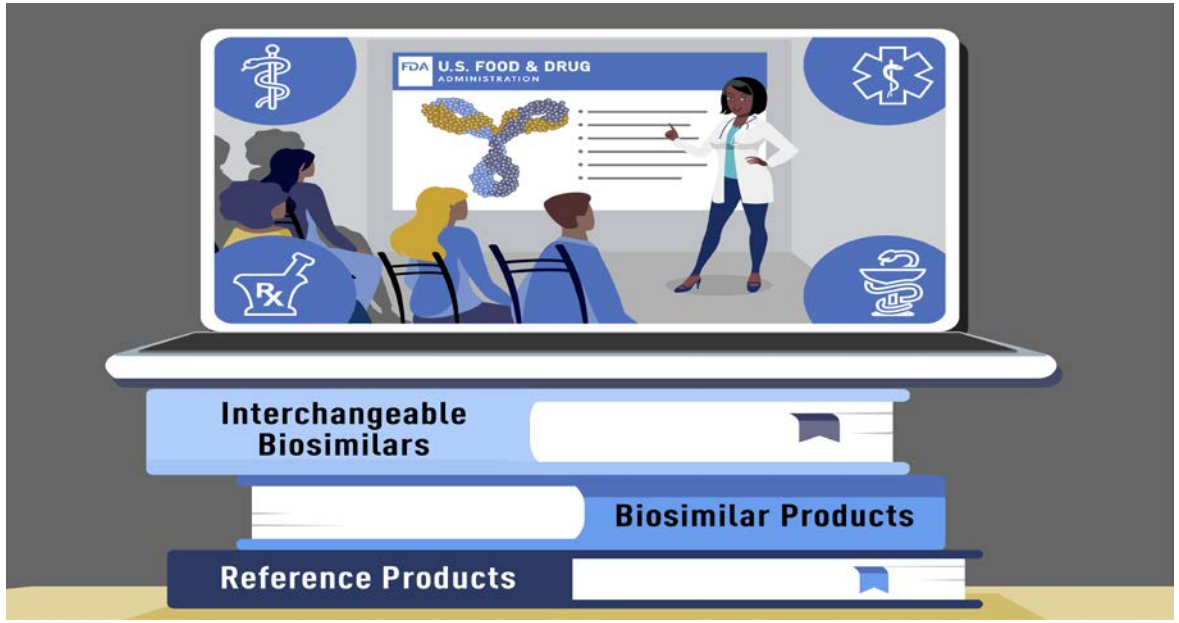
- The Biosimilar Curriculum Toolkit contains multiple types of resources to assist teaching faculty who would like to integrate topics about biosimilars into the training they provide students.

- 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

Web Content and Infographic:

- Uses patient-friendly language and imagery
- Addresses topics, concerns, and misconceptions shown to be most important to patients
- Tested with patients treated with a biologic & patient advocacy organizations

FDA Biosimilar Materials in Spanish

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

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

Future Education and Outreach Plans

- Continue developing materials and resources for patients:
  - Videos
  - Additional infographics and graphics
  - Enhanced Social Media Strategy

- Create additional materials and resources for health care providers:
  - Videos
  - Educational curriculum/teaching resources for medical, nursing, and pharmacy schools
  - Updated Continuing Education Course Options
  - Enhanced Outreach Strategy

- Develop and revise materials as needed based on research/feedback

Resources

- Visit www.fda.gov/biosimilars for access to all the education materials and information about biosimilar and interchangeable products

- Visit the www.fda.gov/purplebook for information on biological products, including if products are biosimilar to a reference product

- Visit www.fda.gov/drugsatfda (**Drugs@FDA**) for information on all CDER approved drug products, including labeling and review information

- Visit https://www.fda.gov/training-and-continuing-education/cderlearn-training-and-education (CDERLearn) for additional training and education opportunities

References

1. FDA website: www.fda.gov/drugs/biosimilars/biosimilar-development-review-and-approval
2. Purple Book: www.fda.gov/purplebook
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4. Datta-Mannan. “ Mechanisms Influencing the Pharmacokinetics and Disposition of Monoclonal Antibodies and Peptides.” *CPT Pharmacometrics Syst Pharmacol*. 2017;6(9):576-588. doi:10.1002/psp4.12224
5. Walsh, G. “Biopharmaceutical benchmarks 2018.” Nat Biotechnol 36, 1136–1145 (2018). https://doi.org/10.1038/nbt.4305
6. Guidance for Industry: Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products. November 2019. https://www.fda.gov/media/133014/download
7. Oncology Drugs Advisory Committee meeting on October 10, 2018. Meeting materials: https://www.fda.gov/advisory-committees/advisory-committee-calendar/meeting-oncologic-drugs-advisory-committee-10102018-10102018#event-materials

Questions?

Thank You

www.fda.gov/biosimilars