Biosimilar Biological Products

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Objectives

- What is a biological product
- Background
- Definitions
  - Reference product
  - Biosimilar biological product
  - Interchangeable biological product
- Bringing biosimilar biological products to US market
  - Evaluation by the FDA
- Questions from consumers, patients, and health care community.

What Is a Biological Product?

- Biological products are medical products used to diagnose, prevent, mitigate, treat, or cure a wide range of diseases and medical conditions, including serious and life-threatening conditions such as cancers.

- Biological products are generally made from a variety of sources, including naturally sourced materials and recombinant DNA technology.

- There are many types of biological products, including proteins, blood products, allergenics, vaccines, tissues, gene and cellular therapies, and xenotransplantation products.

- Some examples of biological products include monoclonal antibodies (e.g., rituximab, infliximab) and therapeutic proteins (e.g., epoetin, filgrastim, etanercept).

What is a Biological Product?

- Link to the FDA Basics webinar presentation on “Overview of Biological Products” held on June 17, 2013:
- https://collaboration.fda.gov/p6nmfvfslmv/?launcher=false&fcsContent=true&pbMode=normal

- Link to the slides presented at the FDA Basics webinar presentation on “Overview of Biological Products” held on June 17, 2013:
- http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM356666.pdf

Background

- The Biologics Price Competition and Innovation Act (BPCI Act) was enacted as part of healthcare reform (Affordable Care Act) that President Obama signed into law on March 23, 2010.

- Goal of the BPCI Act is to encourage the development of biosimilar and interchangeable biological products which can **enhance competition** and may lead to **better patient access** and **lower cost to consumers** for biological products.

- This goal of the BPCI Act is similar to that of the Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act of 1984), that established an abbreviated approval pathway for generic drugs (primarily generic versions of traditional small molecule drugs).

- The BPCI Act creates an **abbreviated pathway** for licensure of biosimilar and interchangeable biological products under **section 351(k)** of the Public Health Service Act (PHS Act).

Definition: Reference Product

The **single** biological product **licensed** by the FDA under **section 351(a)** of the PHS Act, against which a proposed biosimilar biological product is evaluated in its biosimilar application

(Wording is not meant to align directly with statutory language, but provides meaningful explanation for presentation purpose.)

Biosimilar Biological Product?

- Biosimilar biological product is a biological product that has been demonstrated to be biosimilar to the “reference product”

- Biosimilar or Biosimilarity means:

  – that the biological product is **highly similar** to the reference product even if there are minor differences in clinically inactive components; and

  – there are **no clinically meaningful differences** between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(Wording is not meant to align directly with statutory language, but provides meaningful explanation for presentation purpose.)

Interchangeable Biological Product

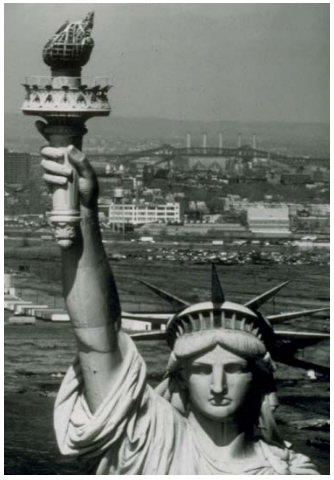
Interchangeable or Interchangeability means that:

- the biological product is **biosimilar** to the reference product;
- it can be expected to produce the **same clinical result** as the reference product **in any given patient**; and
- for a product administered more than once, the **safety and reduced efficacy risks of alternating or switching** are not greater than with repeated use of the reference product.

(Wording is not meant to align directly with statutory language, but provides meaningful explanation for presentation purpose.)

The Desired Product

Analysis of the Desired Product

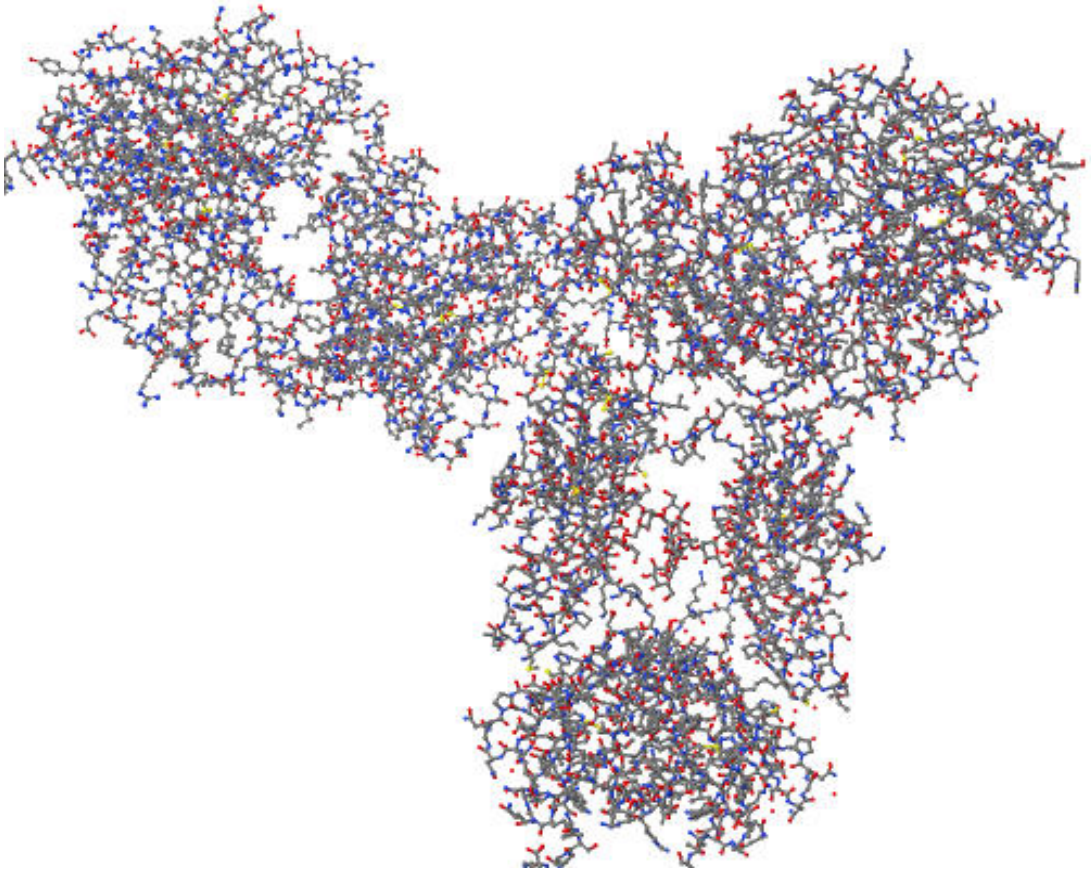





Highly Similar?

Size and Complexity of Therapeutic Products

Aspirin 180 Da
(A small molecule drug)



Bringing a Biosimilar Biological Product to the U.S. Market

A manufacturer who seeks to market a biosimilar biological product must submit a biologics license application (BLA) under section 351(k) of the PHS Act, with scientific data demonstrating, among other things, that the biological product:

- Is **biosimilar** to a reference product;
- Has the same **mechanism(s) of action**, **condition(s) of use, 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.

What is an Abbreviated Licensure Pathway for Biological Products?

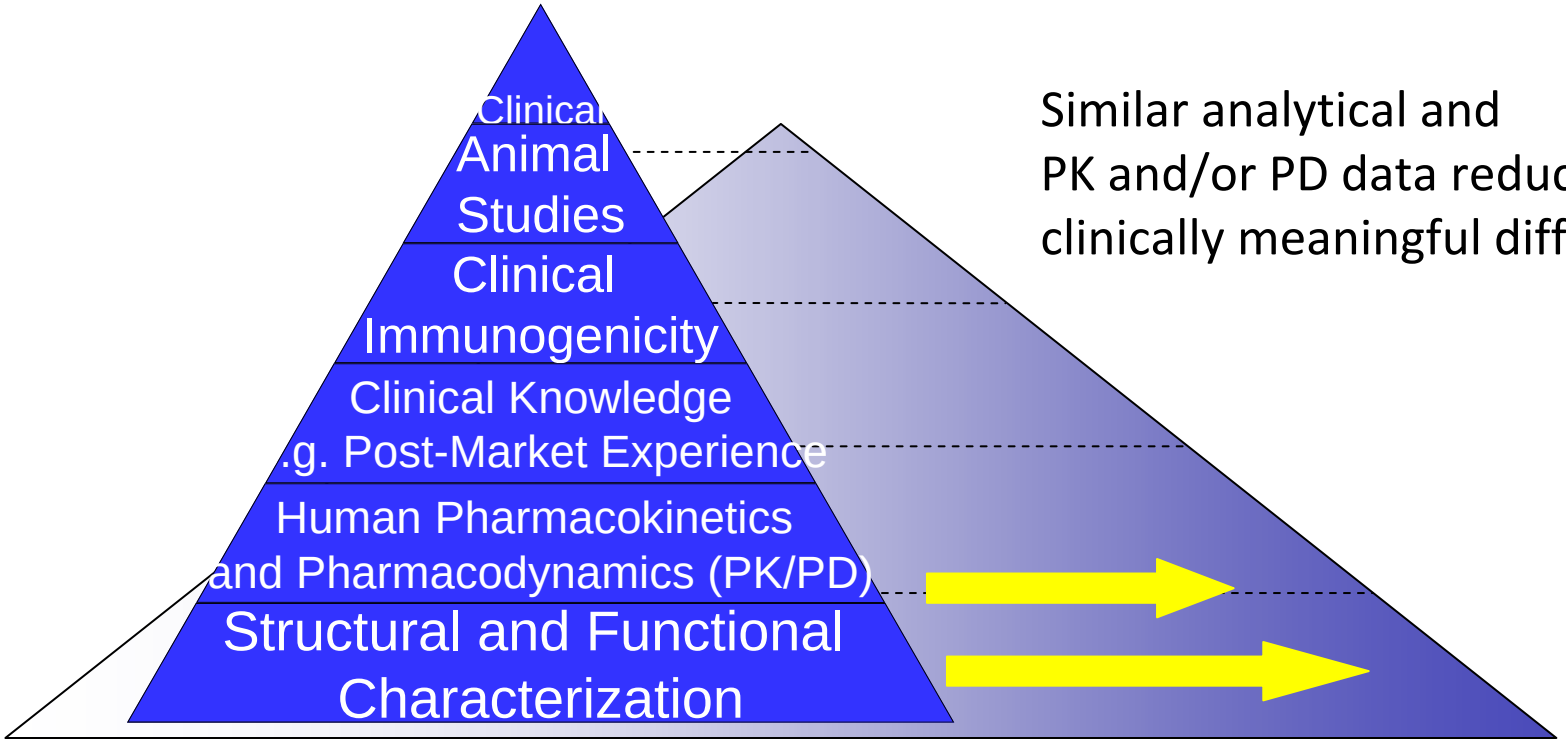
- Section 351(k) of the PHS Act provides an abbreviated licensure pathway for biosimilar or interchangeable biological products.
- A biological product that is demonstrated to be highly similar to an FDA-licensed biological product (the reference product) may rely on certain existing scientific knowledge about the safety, purity, and potency of the reference product
- A biosimilar biological product may not be required to provide full product-specific nonclinical and clinical data to be licensed.

Biosimilar Biological Product Development – Goal

- The goal is to demonstrate biosimilarity between the proposed product and a reference product.
- The goal is not to independently establish safety and effectiveness of the proposed product.

Totality of the Evidence

No “one size fits all” assessment: FDA will evaluate the applicant’s integration of various types of information to provide an overall assessment on whether a biological product is biosimilar to a reference product.



Similar analytical and
PK and/or PD data reduces risk of clinically meaningful differences

Stepwise Approach

Future: Prescribing Biosimilar Biological Products

- Biosimilar biological products will need to be prescribed by the healthcare practitioner.
- Interchangeable biological products may be substituted for the reference product without the intervention of the prescribing healthcare provider.
- Please visit the FDA Biosimilars website for any updates. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.htm

Summary

- Biosimilar and interchangeable biological products can enhance competition and may lead to better patient access and lower cost to consumers for biological products.

- FDA is actively engaging with sponsors interested in developing biosimilar products.

- The scientifically rigorous standards for approval of biosimilar and interchangeable biological products mean that patients and health care professionals can be assured that, when these products go to market, they will meet the standards of safety, efficacy and high quality that everyone expects and counts on.

Thank you!

Questions from consumers, patients, and healthcare community?