



U.S. Food and Drug Administration
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Drugs

Biosimilars

The Patient Protection and Affordable Care Act (Affordable Care Act), signed into law by President Obama on March 23, 2010, amends the Public Health Service Act (PHS Act) to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product. This pathway is provided in the part of the law known as the *Biologics Price Competition and Innovation Act* (BPCI Act). Under the BPCI Act, a biological product may be demonstrated to be "biosimilar" if data show that, among other things, the product is "highly similar" to an already-approved biological product.

Health care professionals and consumers can be assured that FDA will require licensed biosimilar and interchangeable biological products to meet the Agency's exacting standards of safety and efficacy.

Draft Guidances

- [FDA issues draft guidance on biosimilar product development](#)¹
- [Guidance for Industry on Biosimilars: Q & As Regarding Implementation of the BPCI Act of 2009](#)²
- [Federal Register -- Guidance for Industry on Biosimilars: Q & As Regarding Implementation of the BPCI Act of 2009](#)³
- [Scientific Considerations in Demonstrating Biosimilarity to a Reference Product \(PDF - 576KB\)](#)⁴
- [Federal Register -- Scientific Considerations in Demonstrating Biosimilarity to a Reference Product](#)⁵
- [Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product \(PDF - 432KB\)](#)⁶
- [Federal Register -- Quality Considerations in Demonstrating Biosimilarity to Reference Protein Product](#)⁷
- [Fact Sheet: Issuance of Draft Guidances on Biosimilar Product Development](#)⁸
- [Questions and Answers: Issuance of Three Draft Guidance Documents on Biosimilar Product Development](#)⁹
- [Biosimilars Guidance Meeting Webinar 2/15/12](#)¹⁰
- [Download Presentation Slides for 'Biosimilars Guidance Meeting Webinar 2/15/12' \(PDF - 415KB\)](#)¹¹

Related Information

- [Draft Guidances Relating to the Development of Biosimilar Products; Public Hearing; Request for Comments](#)¹²
- [Approval Pathway for Biosimilar and Interchangeable Biological Products Public Meeting](#)¹³
- [Implementation of the Biologics Price Competition and Innovation Act of 2009](#)¹⁴
- [Sections 7001-7003 \(Biologics Price Competition and Innovation Act of 2009\) of the Patient Protection and Affordable Care Act \(Public Law No. 111-148\) \(PDF - 122KB\)](#)¹⁵
- [Biologics Price Competition and Innovation Act of 2009](#)¹⁶

Page Last Updated: 07/10/2012

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