




Biosimilar Pathway

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Biosimilar Pathway

- Biosimilar pathway – balance between innovator and biosimilar product
- Patient Protection and Affordable Care Act (H.R. 3590) which will amend section 351 of Public Health Service Act (PHSA)
 - Passed in March 2010
 - Provides abbreviated biological product license application (aBPL) for biosimilar products



Biosimilar - definition

- “Biosimilar” – “highly similar” to a reference biological product
 - “**highly similar**”: notwithstanding minor differences in clinically inactive components, and for which there are “no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product”

Biosimilar - Requirements

■ aBPL requirements

- Showing of “Biosimilar” by aBPL applicant:
 - Analytical studies to show the biosimilar is highly similar
 - Animal studies
 - Clinical study(ies) including assessment of immunogenicity to demonstrate safety, purity and potency
- biosimilar utilizes the same mechanism of action to a reference product
- Same conditions of use
- Same route of administration, dosage form and strength
- biosimilar manufacturing facility meets appropriate standards
- Secretary, at his discretion, may waive any of the requirements on a case-by-case

Biosimilar - Requirements

- Interchangeable Biosimilar
 - May be distributed without intervention by professional who prescribed reference drug
 - Requirements
 - Biosimilar;
 - Expected to produce the same clinical result as the reference product in “any given patient”; and
 - Risk of safety or diminished efficacy is not greater than the risk of using the innovator product without switch



Biosimilar - PMS

- Post-marketing surveillance (REMS: Risk evaluation and mitigation strategy) requirement applies in the same manner it is applied to innovator biologics



Biosimilar - Requirements

- Guidance for clinical trial and Interchangeability
 - Secretary, at his discretion, may issue guidance documents, with opportunity for public comments
 - Can be general or product specific
 - Issuance of guidance is not pre-requisite for approval of a biosimilar

Biosimilar – Market Exclusivity

- **Innovator Market Exclusivity**
 - biosimilar application may not be filed within 4 yrs after the reference drug was first approved
 - FDA may not approve a biosimilar application until 12 years after the reference product first licensed
 - No new exclusivity for a new indication, new dosage form, strength, administration route of a previously licensed biologic
 - Pediatric exclusivity of 6 months
- **Biosimilar Market Exclusivity**
 - 1 year exclusivity for the first approved interchangeable biosimilar



Notification and Patent Assertion

- **NO Orange Book list**
- Notification and Patent Infringement Action
 - biosimilar applicant notify within 20 days of FDA notice of acceptance to reference product sponsor “confidential access” to a copy of the aBPA and other information describing manufacturing process
 - Confidential information may be used for “sole and exclusive purpose” of determining whether a claim of patent infringement could be “reasonably asserted”
 - This confidential information may not be shared or publicly revealed without prior written consent
 - Reference product sponsor must provide to biosimilar within 60 days,
 - List of patents
 - Identification of patents on the list the sponsor would be willing to license to the biosimilar applicant



Notification and Patent Assertion

- biosimilar Applicant Response within 60 days
 - Detailed “factual and legal” statement on a “claim by claim basis” why patents are invalid, unenforceable or will not be infringed; and/or
 - Statement that biosimilar applicant will not begin market before patent expiration; and
 - A response to the sponsor’s offer to license to specific patents
- Sponsor Reply to biosimilar within 60 days
 - Detailed “factual and legal” statement on a “claim by claim basis” why patents are infringed, valid, and enforceable



Notification and Patent Assertion

- **Good Faith Negotiations & Patent Resolutions**
 - Requires the biosimilar applicant and reference product sponsor to engage in good faith negotiations to determine which listed patents will be the subject of infringement actions
 - If no agreement reached within 15 days, patent resolutions must follow
 - Exchange a list of patent they believe should be the subject of an infringement suit
- **Infringement Suit:**
 - Within 30 days of negotiating the list or after the exchange of the list, reference product sponsor must bring an infringement action for all patents in the list
 - biosimilar applicant provides Department of Health and Human Service with a notice and a copy of the complaint
 - HHS must publish notice of the complaint in FR



Notification and Patent Assertion

- **No 30 month Stay**
 - FDA must approve if biosimilar application satisfies the requirements to show highly similar or interchangeable
- biosimilar applicant notifies the sponsor no later than 180 days before the first commercial marketing of the biosimilar
 - Sponsor may petition for PI after receiving the notice and before the first commercial marketing for any patent that is identified in the list



THANK YOU