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## Biosimilars And Interchangeable Biologics Strategic Elements

**interchangeability, switching and substitution of ...** - substitution of biosimilars: ... deem certain biosimilars as "interchangeable" under u.s. law, interchangeable means: – 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 ...

**the next frontier for improved access to medicines** - this handbook is designed to be a biosimilars and interchangeable biologics reference tool for experts as well as patients. it is important to define terminology

**biologic and biosimilar medicines** - biologic and biosimilar medicines biologic medicines are large, complex molecules that are made in living cells, grown in a laboratory. some examples include vaccines and therapeutic proteins that help your body to fight illnesses such as cancer and arthritis. biosimilars are attempts to copy biologic medicines. however, exact copies of biologic medicines are not possible. biologics are made ...

**biosimilar and interchangeable products: brief update from fda** - or proposed interchangeable products • cder has received meeting requests to discuss the development of biosimilar or ... -understanding of biologics, reference products, biosimilars and interchangeable products. -awareness of fda's role in the biosimilar approval process. -knowledge of the data and information fda reviews/requires to determine biosimilarity. for more information, go ...

**biologic, biosimilar, and interchangeable biologic drug ...** - for biosimilars will be lower than for novel biologics. to evaluate the safety and efficacy of biosimilars to evaluate the safety and efficacy of biosimilars before approval, fda has developed the 351(k) pathway noted earlier.

**understanding reference biologics & biosimilars** - interchangeable, the fda also requires that alternating or switching back and forth between the biosimilar and the reference product should produce similar safety and efficacy results as using the reference product without alternating or switching.5 what does this all mean for people prescribed biologics? if a biologic therapy is prescribed for a chronic condition and a biosimilar becomes ...

**comments from the association for accessible medicines ...** - 2 aam supports pfizer's request for additional guidance on manufacturer communications related to biosimilars and interchangeable biologics.

**customer perspective on biosimilars and interchangeable ...** - february 4, 2014 customer perspective on biosimilars and interchangeable biologics: naming and state legislative issues

**biologics and biosimilars: background and key issues** - biologics and biosimilars: background and key issues congressional research service summary a biological product, or biologic, is a preparation, such as a drug or a vaccine, that is made from

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