



**U.S. Food and Drug Administration**

Protecting and Promoting *Your* Health

## Interchangeability

“Agency officials had telegraphed that interchangeability would be a tough standard to meet. Janet Woodcock, director of the FDA Centre for Drug Evaluation and Research, stated in a *New England Journal of Medicine* commentary that a biosimilar will only be considered interchangeable if it is expected to produce the same clinical result in any patient and that the risk of alternating or switching is no greater than continuing to use the original biological product – essentially copying the statutory language (*US biosimilar rules due by year end, November 23, 2011*).”



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## Information for Consumers (Biosimilars)

**Will biosimilars be dispensed in place of the biological product they have been compared to in every situation?**

- Only if they are interchangeable. Biosimilar biological products cannot be dispensed in place of another biological product unless a physician or other healthcare professional prescribes the biosimilar product. However, biological products that are “interchangeable” will be able to be substituted with certain biological products, as described below.
- An “interchangeable” biological product is biosimilar to the reference product, and can be expected to produce the same clinical result as the reference product in any given patient. If administered more than once to an individual (as many biological products are), the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product will not be greater than the risk of using the reference product without such alternation or switch.
- Once determined “interchangeable” two biological products will thus be able to be substituted for each other (i.e., interchanged) by a pharmacist without the intervention of the health care provider.
- Pharmacists will be responsible for knowing which biological products are interchangeable and which will require prescriber prescription before substitution.

## Information for Healthcare Professionals (Biosimilars)

- Biosimilarity** means that the biological product is highly similar to the U.S.-licensed reference biological product notwithstanding minor differences in clinically inactive components; and that there are no clinically meaningful differences between the biologic product and the reference product in terms of the safety, purity, and potency of the product.
- Interchangeability** means that the biologic product is biosimilar to the U.S.-licensed reference biological product and can be expected to produce the same clinical result as the reference product in any given patient. ***For a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product will not be greater than the risk of using the reference product without such alternation or switch.*** Interchangeable biological products may be substituted at the pharmacy level without the intervention of a healthcare provider.