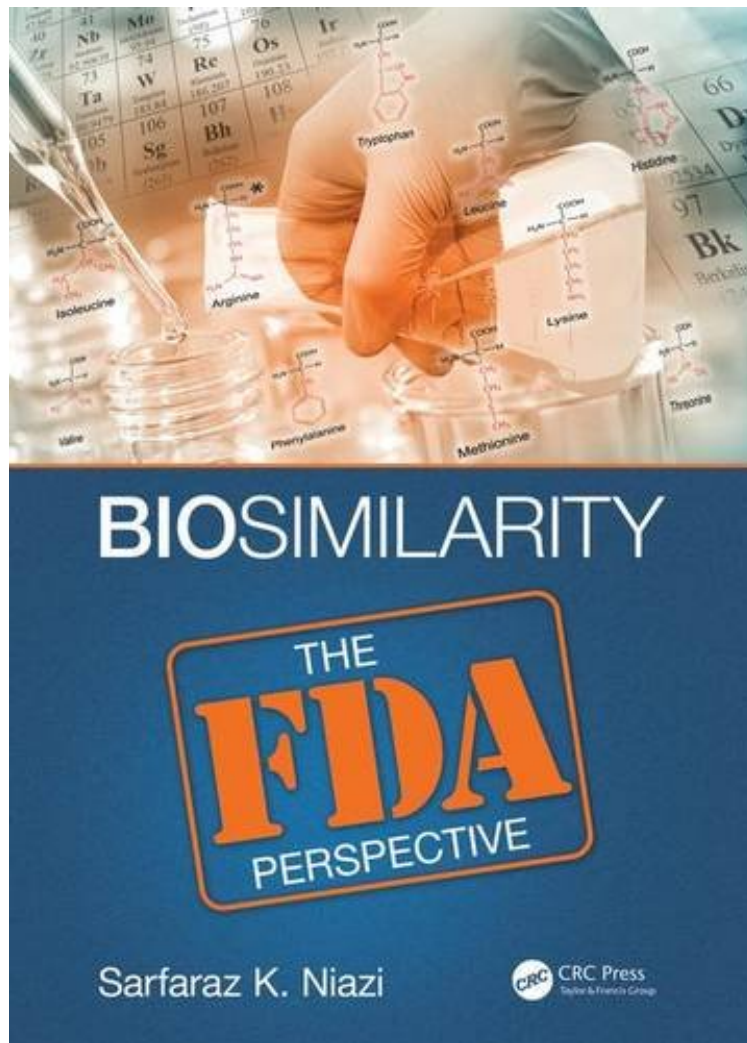


(Free) Biosimilarity: The FDA Perspective

## Biosimilarity: The FDA Perspective

*Sarfaraz K. Niazi*

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**Sarfaraz K. Niazi : Biosimilarity: The FDA Perspective** before purchasing it in order to gauge whether or not it would be worth my time, and all praised Biosimilarity: The FDA Perspective:

The focus of this book is on how the US FDA will approve biosimilar drugs. The European scene is well developed with specific guidelines that are already in place. However, these guidelines do not apply to the thinking of the FDA in approving these products. The FDA is quite different from other regulatory agencies. With the US providing more than 50% of the worldwide market for these products, every serious manufacturer of biosimilar biological drugs

should be targeting US approval of their products. Thus, this book is strictly on FDA approval strategy.