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Rheumatology leaders say FDA biosimilar interchangeability guidance a balanced approach

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The Food and Drug Administration (FDA) has released a draft guidance on biosimilar interchangeability titled "Considerations in Demonstrating Interchangeability With a Reference Product" that leaders at the American College of Rheumatology (ACR) believe may address many of the safety and efficacy concerns physicians have raised over the past year.

"The ACR is pleased to see the FDA issue draft guidance on biosimilar interchangeability," expressed Dr. Angus Worthing, MD, FACP, chair of the ACR's Government Affairs Committee. "This guidance brings us one step closer to the shared goal of lowering prices in the biologics marketplace. While the ACR is still reviewing the document and will provide detailed comments to the FDA in the coming weeks, our initial reaction is that the draft guidance strikes a good balance between ensuring safety and efficacy while also getting biosimilar products to market as efficiently as possible."

"We also applaud the FDA for suggesting clinical studies which switch back and forth, not just one-way from the reference drug to the biosimilar. The use of at least two exposure periods to each drug will mimic to some extent what our patients are likely to experience with changing formularies in a multi-payer, multi-state, ever-changing market."

More information: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537135.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

Provided by American College of Rheumatology