799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

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Submitted via the Federal eRulemaking Portal: http://www.regulations.gov

Martin Makary, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

**Re: Draft Guidance for Industry, "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies" (Docket No. FDA-2011-D-0605)**

Dear Commissioner Makary:

Vizient, Inc. appreciates the opportunity to comment on the Food and Drug Administration's (FDA) recently published draft guidance for industry, "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies" (hereinafter, Draft Guidance). Vizient also appreciates FDA's efforts to streamline approvals for biosimilar products and enhance competition. We applaud the FDA's decision to clarify the circumstances in which comparative effectiveness studies (CES) are not needed to support a demonstration of biosimilarity.

## Background

Vizient, Inc., the nation's largest provider-driven healthcare performance improvement company, serves more than 65% of the nation's acute care providers, including 97% of the nation's academic medical centers, and more than 35% of the non-acute market. The Vizient contract portfolio represents $140 billion in annual purchasing volume enabling the delivery of cost-effective, high-value care. With its acquisition of Kaufman Hall in 2024, Vizient expanded its advisory services to help providers achieve financial, strategic, clinical and operational excellence. Headquartered in Irving, Texas, Vizient has offices throughout the United States. Learn more at www.vizientinc.com.

## Recommendations

Vizient has long supported the introduction and adoption of biosimilars as safe and effective alternatives to originator biologics and continues to provide education to providers to remove barriers to product acceptance. Also, Vizient's 2022 survey regarding biosimilar adoption highlights several opportunities to enhance biosimilar utilization. Further, Vizient's Summer 2025 Spend Management Outlook indicates that biosimilar competition for certain agents is influencing lower price trends. Vizient strongly believes that biosimilars are a critical component of the ongoing efforts to minimize health care costs and mitigate increasing drug expenditures to preserve access to care

Vizient endorses policy provided in the Draft Guidance, particularly the recommendation that "sponsors consider a streamlined approach where a CES may not be necessary to support a

demonstration of biosimilarity"[1] which eases requirements for approval while maintaining safety. Vizient appreciates that the Draft Guidance highlights the sensitivity of a comparative analytical assessment (CAA), which is less burdensome than a CES, and incorporates these findings into new policy outlined in the Draft Guidance. Vizient believes this change will help reduce the costs and time associated with biosimilar development and approval thus sustaining and expanding the investment interest of prospective manufacturers in bringing much needed competition to the market. As such, Vizient encourages FDA to finalize the Draft Guidance.

While not addressed in the Draft Guidance, Vizient also applauds the FDA for recognizing the importance of removing the interchangeability designation during a recent press conference.[2] While the current legislative framework regarding biosimilars addresses interchangeability, Vizient looks forward to learning more about FDA's separate initiative to make it easier for biosimilars to be developed as interchangeable with brand-name biologics.[3] We recommend that FDA promptly advance this initiative which we anticipate will enhance competition and improve patient access to critical treatments.

## Conclusion

In closing, on behalf of Vizient, I would like to thank the FDA for providing this opportunity to comment on this important Draft Guidance. Vizient looks forward to continuing to work with the FDA to support strategies that increase biosimilar adoption, minimize health care costs and mitigate increasing drug expenditures to preserve access to care. Please feel free to contact me at (202) 354-2607 or Jenna Stern at jenna.stern@vizientinc.com or (202) 354-2673 if you have any questions or if Vizient can provide any assistance as you consider these issues.

Respectfully submitted,

Shoshana Krilow
Vice President of Public Policy and Government Relations
Vizient, Inc.

[1] As provided in the Draft Guidance, FDA indicates, "A streamlined approach should be considered when:
• The reference product and proposed biosimilar product are manufactured from clonal cell 110 lines, are highly purified, and can be well-characterized analytically;
• The relationship between quality attributes and clinical efficacy is generally understood for the reference product, and these attributes can be evaluated by assays included in the CAA; and
• A human pharmacokinetic similarity study is feasible and clinically relevant."
[2] Biosimilars Reform (Oct. 29, 2025), available at: https://www.hhs.gov/live/index.html
[3] https://www.fda.gov/news-events/press-announcements/fda-moves-accelerate-biosimilar-development-and-lower-drug-costs