

January 27, 2020

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

Stephen M. Hahn, 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Re: Draft Guidance for Industry, “Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products” (Docket No. FDA-2019-D-5255)

Dear Commissioner Hahn:

Vizient, Inc. appreciates the opportunity to comment on the Food and Drug Administration’s (FDA) recently published draft guidance for industry, “Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products.” Vizient also appreciates FDA’s ongoing development and implementation of the provisions of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). We applaud the FDA’s thoughtful approach, ongoing commitment to increased awareness of biologic manufacturing and regulatory principles, and furthermore the application of scientifically based decision-making in the introduction of biosimilar medications.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 50% of the nation’s acute care providers, which includes 95% of the nation’s academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than \$100 billion in annual group purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Comments

Vizient has supported the introduction and adoption of biosimilars as safe and effective alternatives to originator biologics over this first decade of their inception and continues to provide education to physicians and other providers to remove barriers to product acceptance. We strongly believe 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 has recently launched a new and enhanced suite of clinical and financial resources to support our members in evaluating the opportunity biosimilars provide to them as well as the patient populations they serve. In addition, Vizient has approximately 75 sourcing, clinical, analytics, and consulting-focused pharmacists and other experts supporting biosimilar related initiatives. In spite of all of this engagement, additional assistance is required and we welcome and appreciate the actions taken by the FDA.

Vizient fully endorses the FDA's guidance that "a comparative clinical immunogenicity study generally would be unnecessary to support a demonstration of biosimilarity or interchangeability"¹ when "a comparative analytical assessment based on state-of-the-art technology supports a demonstration of 'highly similar' for a proposed biosimilar or interchangeable insulin product".² Given the strength of analytical characterization data, the less complex structure of insulin, and the absence of a clinical impact of immunogenicity with insulin use, this approach is scientifically justified. By limiting unnecessary clinical data requirements, the approval process for biosimilar insulins, including approvals for interchangeable insulins, can be made more effective and efficient.

In addition, Vizient encourages the FDA to identify other biological products beyond insulin for which clinical data requirements are unnecessary. Given the continuing concern about pharmaceutical expense, any scientifically justified strategies that could expedite biosimilar development and approval are desperately needed. We applaud the FDA's efforts and recommend the application of this same logic to other biological products.

Vizient appreciates the FDA's willingness to convene events such as the May 2019 public meeting, "The Future of Insulin Biosimilars: Increasing Access and Facilitating the Efficient Development Biosimilar and Interchangeable Insulin Products." We further thank the FDA for its willingness to use the feedback provided in this public meeting, including a presentation from Vizient, in its development of this most recent draft guidance.

Conclusion

In closing, on behalf of Vizient, I would like to thank the FDA for providing us 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,



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Vizient, Inc.

¹ U.S. Food and Drug Administration, (November 2019). Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products Draft Guidance, 100-102.

² U.S. Food and Drug Administration, (November 2019). Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products Draft Guidance, 95-97.