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FDA Issues “Biosimilars” Draft Guidelines

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Advisory

On February 9, 2012, the U.S. Food and Drug Administration (FDA) issued three draft guidance documents– the first since the Biologics Price Competition and Innovation Act passed in March 2010 – for the development of biosimilars. The biosimilars market is expected to reach $8 billion by 2020. The three guidance documents are:

- Scientific Considerations in Demonstrating Biosimilarity to a Reference Product
- Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product
- Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009

These highly anticipated documents, which appear to be in line with both prior FDA indications and industry expectations, offer insight as to how to establish biosimilarity.

The FDA made clear that it intends to use a risk-based ***totality of the evidence*** approach to evaluate data and information submitted by sponsors in support of biosimilarity, varying the type and amount of analyses and testing dependent on the product. While most cases will require animal and human studies, there may be instances where those requirements are waived. The FDA recommends that sponsors use a ***stepwise*** approach in developing their evidence, ensuring that development at each step evaluates uncertainty and identifies next steps to address that uncertainty. Establishing interchangeability, which would allow payers and pharmacists to automatically substitute the biosimilar for the branded biologic, would undoubtedly require additional studies. Rachel Sherman, FDA associate director for medical policy, was quoted in *The Wall Street Journal*, about the program: "We're trying to send the signal that it's not one-size-fits-all. It's product-by-product."

While the FDA has yet to receive its first biosimilar application (BLA), these guidance documents are a first – but important – step in bringing biosimilars to market. The documents represent the FDA’s current thinking on the regulatory process, but are *draft* documents for which the FDA is seeking public comment from stakeholders and interested parties. Any potentially affected or interested parties, from brand biologics companies to generics and biosimilars developers and manufacturers, to patient consumers should submit their comments within 60 days of publication of the Federal Register notice.

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