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INTELLECTUAL PROPERTY DEPARTMENT

ALERT

FDA ISSUES GUIDANCE ON BIOSIMILARS

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On Feb. 9, 2012, the U.S. Food and Drug Administration (FDA) issued three draft guidance documents on biosimilar product development in the United States. The guidance documents outline some of the scientific and quality issues with developing biosimilars, as well as industry questions about the implementation of the Biologics Price Competition and Innovation Act, part of the Patient Protection and Affordable Care Act.

The healthcare law created an approval pathway for biosimilars, or follow-on biologics, which are generic versions of protein-based products. The FDA said in the guidance documents that it expects biosimilars to be "highly similar" to the reference product, which is the original biological product that received approval.

Dr. Janet Woodcock, director of FDA's Center for Drug Evaluation and Research, stated in a news release, "These draft documents are designed to help industry develop biosimilar versions of currently approved biological products, which can enhance competition and may lead to better patient access and lower cost to consumers."

As the cornerstone for demonstrating biosimilarity, the guidelines call for a stepwise approach to assess structural and functional characterization of both the proposed product and the reference product. Ultimately, based on the totality of evidence, no clinically meaningful difference should exist between the proposed and reference products. The FDA will seek public comment on the guidance documents during a 60-day comment period. Instructions on how to submit comments will be announced in an upcoming Federal Register notice.

Fox Rothschild will report on important developments as they occur. If you have questions about this Alert or would like information on becoming involved in the comment development process, please contact Gerard P. Norton at 609.844.3020 or gnorton@foxrothschild.com or Shahnam Sharareh at 609.844.3030 or sshareh@foxrothschild.com or any member of Fox Rothschild's Intellectual Property Department.

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