FDA Issues Revised Final Guidance On Biosimilar Development And The BPCI Act

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On September 20, 2021, the U.S. Food and Drug Administration (FDA) announced the availability of its revised final guidance for industry on biosimilar development and the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). Titled “Questions and Answers on Biosimilar Development and the BPCI Act,” the revised guidance aims to inform prospective applicants and facilitate the development of...
proposed biosimilars and proposed interchangeable biosimilars. The guidance also includes FDA’s interpretation of certain statutory requirements added by the BPCI Act.

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