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HHS Announces Availability Of Draft Guidance On Therapeutic Protein Biosimilars

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On May 22, 2019, the U.S. Food and Drug Administration's (FDA) Department of Health and Human Services (HHS) announced via the *Federal Register* the availability of a draft guidance for industry titled "Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations." The draft guidance is a revision of the 2015 guidance titled "Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product." It provides recommendations on the design and evaluation of comparative analytical studies that intend to demonstrate that a proposed therapeutic protein product is biosimilar to a reference product licensed under the Public Health Service Act (PHS Act). Additionally, the draft guidance makes recommendations to sponsors on the scientific and technical information for the chemistry, manufacturing, and controls (CMC) portion of a marketing application. Comments on the draft guidance are due on or prior to **July 22, 2019**.

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