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Second U.S. Biosimilar Approval Shows FDA's Confidence

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ATTORNEYS

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Axinn counsel Stacie Ropka was quoted in the Bloomberg BNA article, "Second U.S. Biosimilar Approval Shows FDA's Confidence."

In reaction to the FDA's April 5 approval of Pfizer's and Celltrion's Inflectra as a biosimilar of Johnson & Johnson's arthritis treatment Remicade (infliximab), Stacie said, "this signals that the Food and Drug Administration has confidence in its approval process and confidence to okay something as complex as a biosimilar of a monoclonal antibody as well as extrapolations across seven indications of the original biologic or reference product." Stacie also commented that, "since the FDA now knows the type of data it requires for biosimilars of both straight-forward and complex biologics, I would think it would say to other biosimilar applicants, 'This type of data has worked for us.' That is not to say that it's still not going to be on a case-by-case basis. But there's no denying this is a big step forward for biosimilars in that it should encourage other biosimilar developers."

Click here to read the article in its entirety.