

No orange book, no problem: Due diligence for biologics and biosimilars

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Over the past twenty-eight years, branded and generic pharmaceutical companies have come to rely on the FDA's Orange Book to identify the relevant patents covering pharmaceuticals. The regulations set forth in the Biologics Price, Competition, and Innovation Act ("BPCIA"), which govern the FDA approval process for biologics and biosimilars, however, do not require companies to publicly list patents covering branded biological products. As such, companies are forced to conduct their own due diligence to identify relevant patents. This session will address the patent disclosure requirements in the BPCIA and discuss due diligence tips and tactics for both branded and biosimilar companies seeking to identify relevant patents protecting FDA approved biologics.

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