

Morgan Lewis



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Legislative Updates

- > **On September 20, 2021, FDA issued two guidance documents:**
 - > Questions and Answers on Biosimilar Development and the BPCI Act
 - > New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 3)
 - > In both documents, FDA states that each provides “answers to common questions from prospective applicants and other interested parties” regarding the BPCIA

- > **On July 29, 2021, the Senate Judiciary Committee's antitrust panel advanced a biosimilar-related bill**
 - > Bill seeks to prohibit biological product manufacturers from compensating biosimilar companies in exchange for the biosimilar company delaying entry into the market

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