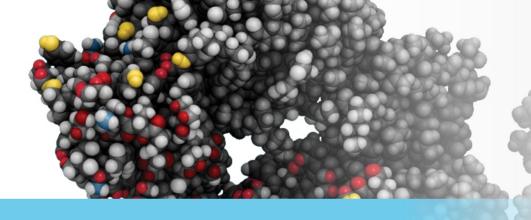
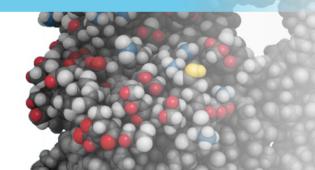
Morgan Lewis



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Legislative Updates



Legislative Updates

> President signed Consolidated Appropriations Act on December 27, 2020

- > Permits, but does not require, aBLAs to include information showing that the biosimilar's conditions of use are the same as conditions of use approved
- > Requires FDA to create a searchable electronic list of licensed biologics, provide monthly updates to the list, and include in the list exclusivities and patent information included on (3)(A) lists
 - > A request for public comment will occur in 2023 regarding what should be added to or deleted from the list

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