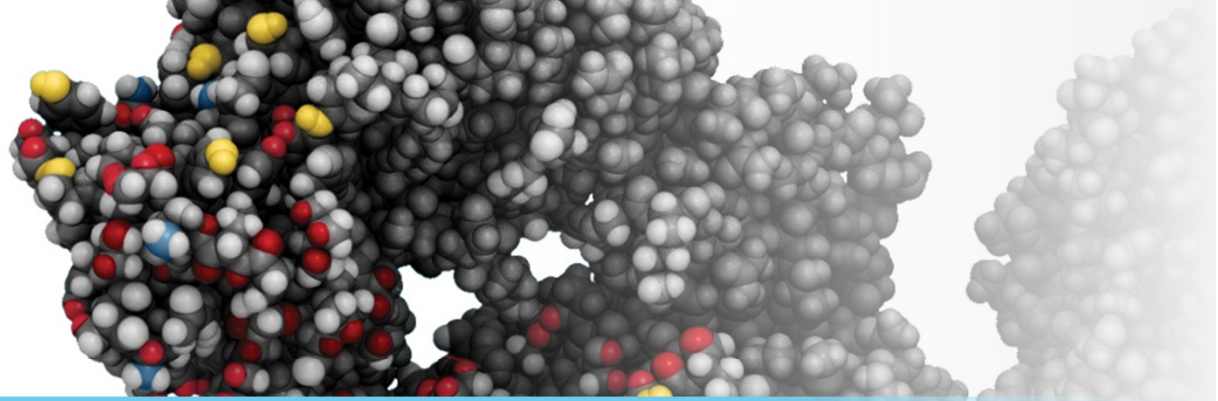
Morgan Lewis



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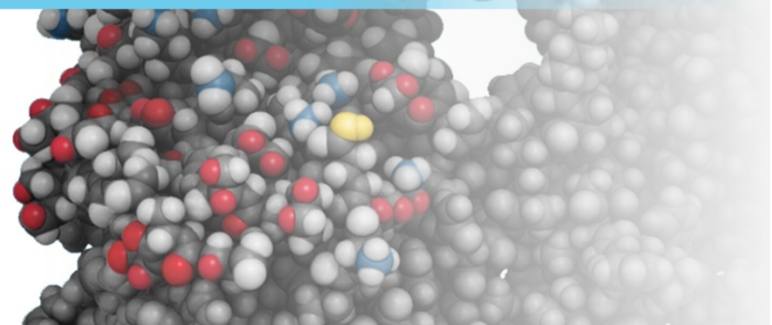
Legislative and Regulatory Updates



Interchangeability and Switching Studies

- As of late, FDA (and Congress) have been weighing the continued distinction between licensed biosimilars and interchangeable biosimilars.
- To be licensed as an interchangeable biosimilar under the Public Health Service Act a product must:
  - Meet the standards of biosimilarity;
  - Establish that the product can be expected to produce the same clinical result as the reference product in any given patient; and
  - For products administered more than once, that the risk of alternating or switching between the biosimilar and the reference product is not greater than using the reference product alone (the "switching standard").
- FDA's Interchangeability Guidance has recommended data from switching studies to satisfy the switching standard.
- In June 2024, FDA announced via a new draft guidance that it intends to revise the Interchangeability Guidance to clarify that in lieu of switching studies, an assessment of why comparative analytical and clinical data provided in the 351(k) BLA may satisfy the requirements of the switching standard.
- In addition to potentially easing data requirements for a biosimilar to receive the interchangeability designation, this development may also reflect a narrowing of distinctions between the two biosimilar designations.

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