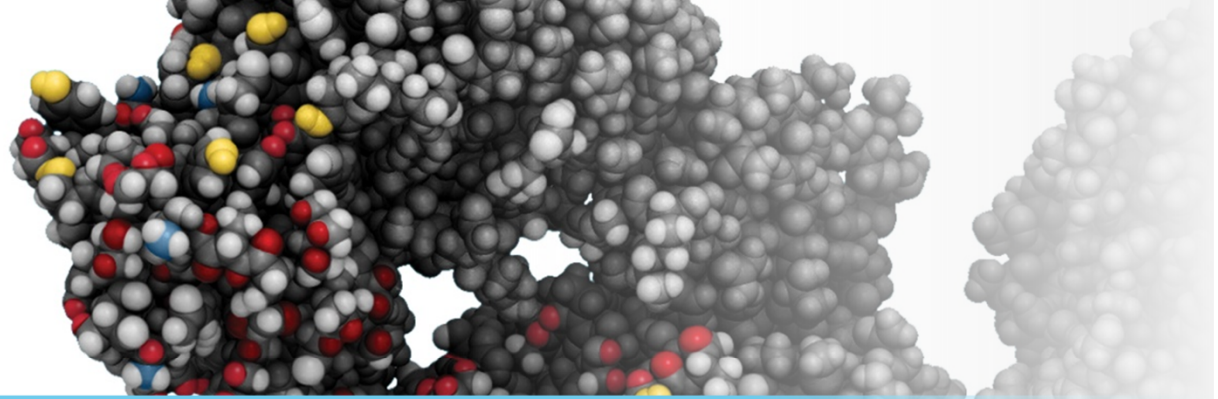
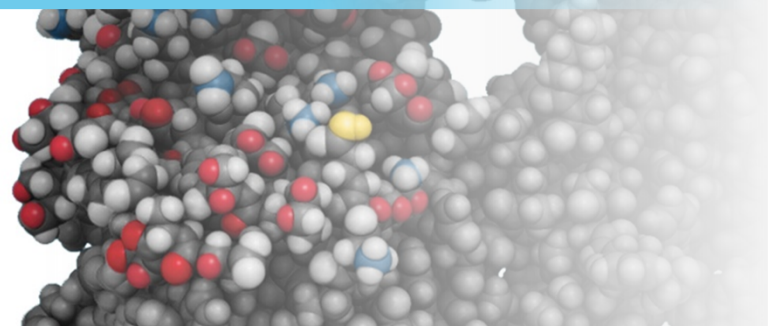
Morgan Lewis



BLOCKBUSTER BIOLOGICS REVIEW ISSUE 26

Legislative and Regulatory Updates



Senators Introduce Bipartisan "Skinny Labels, Big Savings Act"

- On December 19, 2024, Senators John Hickenlooper (D-Colo.), Tom Cotton (R-Ark.), Peter Welch (D-Vt.), and Susan Collins (R-Maine) introduced the bipartisan "Skinny Labels, Big Savings Act."
- This legislation aims to lower drug prices and create legal protections for generic and biosimilar drug manufacturers who obtain "skinny label" FDA approvals.
  - Federal law permits FDA to approve generic and biosimilar drugs via a "skinny label" that carves out indications protected by existing patents or regulatory exclusivities.
  - This legislation is intended to provide a pathway for manufacturers to more quickly launch a generic or biosimilar version of a product with unpatented uses without the risk of costly litigation.
- Specifically, this legislation would amend federal patent infringement law so that the following actions are not considered violations of a method of use patent claim:
  - Submitting or seeking approval of a skinny label for a generic or biosimilar pharmaceutical product;
  - Labeling, promoting, or commercially marketing a drug with skinny labeling approved by the FDA; and
  - Describing, consistent with the Federal Food, Drug, and Cosmetic Act, a drug approved via skinny label as a generic of or therapeutic equivalent to the branded drug.

CDER Releases 2025 Guidance Agenda with Plans for Biosimilars

The FDA's Center for Drug Evaluation and Research (CDER) released its annual guidance agenda, describing guidance documents that it intends to publish in 2025. Appearance of a document on the guidance agenda does not guarantee timely publication from FDA, although it does typically indicate an area of active interest from the FDA staff.

In its current iteration, CDER's guidance agenda includes a number of topics specifically geared to biosimilar programs:

- *New Guidance*: Exclusivity for First Interchangeable Biosimilar Biological Products
- *Revised Guidance*: Scientific Considerations in Demonstrating Biosimilarity to a Reference Product
- *New Guidance*: Biosimilar and Interchangeable Biosimilar Products: Considerations for Container Closure Systems and Device Constituent Parts
- *New Guidance*: Pediatric Study Plans for Biosimilar Products

Contacts

Christopher J. Betti, Ph.D.
Chicago
T: +1.312.324.1449
christopher.betti@
morganlewis.com

Kelly A. Plummer, Ph.D.
Chicago
T: +1.312.324.1490
kelly.plummer@
morganlewis.com

Maarika L. Kimbrell
Washington, DC
T: +1.202.739.5348
maarika.kimbrell@
morganlewis.com

Maria E. Doukas
Chicago
T: +1.312.324.1454
maria.doukas@
morganlewis.com

Margaret C. Harney
Chicago
T: +1.312.324.1727
margaret.harney@
morganlewis.com