

# Morgan Lewis



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## **Legislative and Regulatory Updates**

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- > **On March 7, 2022, the FDA announced that it is offering funding for several research proposals under the regulatory science pilot for biosimilars under the upcoming Biosimilar User Fee Amendments (BsUFA III) program.**
  - > The five-year program, which will run from FY2023-2027, must still be approved by Congress.
  - > The broad goals of the program are to advance the development of interchangeable products and to make biosimilar development more efficient.
    - > Up to five awards of \$1 million-\$2 million possible.
    - > The FDA said “a variety of project types are welcomed under this FOA [funding opportunity announcement], including analytical methodology (including bioassay) development, in silico tools, real world evidence, pharmacology studies, ancillary studies in parallel to planned or ongoing clinical trials, and combinations of these project types.”

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