S. 1414, Expedited Access to Biosimilars Act

Section 1. Short Title.
This section provides that the Act may be cited as the "Expedited Access to Biosimilars Act."

Section 2. Assessment of Immunogenicity, Pharmacodynamics, or Comparative Clinical Efficacy in Clinical Studies Required for Licensure of Biological Products as Biosimilar.
This section eliminates the default requirement for studies assessing immunogenicity, pharmacodynamics, or comparative clinical efficacy while giving the Secretary the discretion to reimpose these study requirements on a case-by-case basis.