

Insights: Publications

Drug to Biologic Transition: Is Purple The New Orange?

Kilpatrick Townsend MEMO|Biopharma Industry Blog

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The regulatory approval pathway for a new “biological product” submitted as a Biologics License Application (BLA) under the Biologics Price Competition and Innovation Act (BPCIA), is now separate from the approval process for a new “drug” product submitted as a New Drug Application (NDA) under the Hatch-Waxman Act. Two separate searchable online databases now exist for approved “drug” and “biological” products, respectively; the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book), and the Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book).

Related People



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