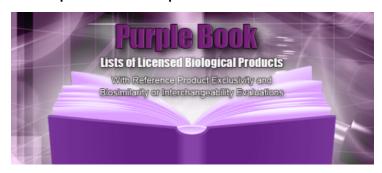


## **USFDA** publishes its 'Purple Book'

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The lists include the date a biological product was licensed under 351(a) of the PHS Act, and whether FDA evaluated the biological product for reference product exclusivity under section 351(k)(7) of the PHS Act.

The Purple Book will also enable a user to see whether a biological product licensed under section 351(k) of the PHS Act has been determined by FDA to be biosimilar to or interchangeable with a reference biological product (an already-licensed FDA biological product).

Biosimilar and interchangeable biological products licensed under section 351(k) of the PHS Act will be listed under the reference product to which biosimilarity or interchangeability was demonstrated.

Separate lists for those biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) will be updated periodically.