

## FDA Throws the (Purple) Book at Biosimilars - Purple v. Orange

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**PRACTICES** Life Sciences, Patents, Intellectual Property, Hatch-Waxman/ANDA, Biosimilars

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On September 9, 2014, the U.S. Food and Drug Administration (FDA) published the inaugural “Purple Book,” a list of approved or “licensed” biological products, including all biosimilar and interchangeable biological products. The Purple Book is more formally known as “Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations.” The Purple Book is meant, at a fundamental level, to be the biological equivalent of the “Orange Book.” While the Orange Book lists small molecule reference listed drugs and their approved counterpart generic drugs, the Purple Book lists licensed biologics and will list the corresponding licensed biosimilars once any are approved in due course.

The Purple Book includes two (2) lists. One list includes biologics approved by the FDA’s Center for Drug Evaluation and Research (CDER) and the other list includes biologics approved by the FDA’s Center for Biologic Evaluation and Research (CBER). Licensed biosimilar and interchangeable biological products will be listed under the reference product to which biosimilarity and interchangeability was demonstrated. To date, only a few publicly known biosimilar applications have been filed—including by Sandoz and Celltrion. More filings are expected, however, in the near future.

***To read the full alert, click on the PDF linked below.***

[FDA-Purple-Book-v-Orange-Book.pdf](#)

Please contact the authors to learn more about the patent issues involved in bringing a biosimilar or interchangeable biologic drug candidate to market.

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