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News Update

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

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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.

Each Purple Book list includes:

1. the biologic license application (BLA) number;
2. product name (nonproprietary name);
3. proprietary name (brand/trade name);
4. date of licensure (date the product was approved for marketing);
5. date of first licensure (date from which reference product exclusivity began to run);
6. reference product exclusivity expiry date (date that indicates the date that is 12 years from the date of first licensure plus any granted pediatric exclusivity);
7. whether the product is interchangeable ("I") or biosimilar ("B"); and
8. whether the product has been withdrawn or is no longer being marketed.

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Thus, the Purple Book is similar to the Orange Book in that it lists certain products, their approval dates, and exclusivity information. Comparable to the Orange Book, the Purple Book will help pharmaceutical enterprises determine if a particular biologic product has been designated by the FDA to be biosimilar to, or interchangeable with, a reference product. On the other hand, the lack of an expiration date listing does not mean the product is ineligible or that the date has passed—it just means that the FDA has not evaluated it. This is an important caveat on the details listed in the Purple Book, and is quite different from the more definitive Orange Book expiration date listings.

A significant difference from the Orange Book, however, is that the Purple Book does not include patent information for the reference biological product. This is due, at least in part, to the different patent resolution process in place for biological products. Under the complex patent dance of the Biologics Price Competition and Innovation Act, the biological applicant and reference product sponsor are expected to provide and exchange a list of patents that each believes covers the biological product while narrowing down the issues of dispute between the two stakeholders.

Another difference is that the Purple Book is not, as of yet, easily searchable. While the FDA has an easy-to-use, reasonably sophisticated website for the Orange Book where a user can search by active ingredient, proprietary name, patent, applicant holder, or application number, in most cases for prescription, over-the-counter (OTC), and discontinued products, there is no similar search mechanism for the Purple Book. Instead, the FDA provides only the two lists in PDF format. As the Purple Book is expanded, the FDA will presumably improve the searchability as it has done with the Orange Book.

Although the information contained in the Purple Book may not be as comprehensive as that in the Orange Book so far, the Purple Book is still a valuable reference tool in developing a biosimilar or interchangeable biologic product. As biosimilar products are approved, the Purple Book will be updated to include more information for biosimilar applicants and reference product sponsors alike. The Purple Book is available at the bottom of the page here.

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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