Friday, February 28, 2020

On February 24, 2020, FDA Commissioner Stephen M. Hahn, M.D., announced that FDA is upgrading its Purple Book, which is otherwise known as its “Database of FDA-Licensed Biological Products.” According to Dr. Hahn, FDA is working to expand the Purple Book by transitioning from its current list format to a searchable online database for all approved biosimilar products and their reference products. An upgrade planned to be released in multiple phases, the full search functionality is the first step. Subsequent phases will include the expansion of the number of FDA-licensed biological products included in the Purple Book online database until the final release, which will include information about all FDA-licensed biological products. The aim is to grow the data set to include data and information about all Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation
and Research (CDER) regulated products.

The first phase of the upgrade includes information about a product’s proprietary and proper names, the full product label, dosage form, route of administration, strength, and marketing status, among other information. FDA plans to open a public docket to gather feedback from stakeholders on the new database with its enhanced functionality. In the announcement, Dr. Hahn stated that “[t]his expansion and digitization of the Purple Book will make more information about FDA-licensed biological products more accessible, increasing transparency for patients, industry users and other stakeholders.”

**FDA Issues Final Rule Amending The Definition Of “Biological Product”**

On February 21, 2020, the U.S. Food and Drug Administration (FDA) issued a final rule to amend its regulation that defines “biological product.” The new definition incorporates changes made by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) and the Further Consolidated Appropriations Act, 2020 (FCA Act). Under the final rule, the statutory term “protein” is interpreted to mean any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. Intended to clarify the statutory framework under which such products are regulated, the final rule will be effective on **March 23, 2020**.

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