It's All in the Name: Updated FDA Guidance on Nonproprietary Naming of Biologic Products

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In January 2017, the FDA published guidance that adopted a naming convention that attaches a distinguishing suffix to the proper names[1] of both originator and biosimilar biological products. The guidance also noted that the FDA was considering retrospectively changing the names of biological products already on the market to add distinguishing suffixes.

On March 7, 2019, the FDA published draft guidance that updates the January 2017 guidance document. First, the FDA determined that the proper names of biological products that have already been licensed or approved under the Public Health Service Act (PHS Act) and that do not include an FDA-designated suffix in their proper names need not be revised. Similarly, the FDA indicated that it does not intend to apply the naming convention to transition biological products, which are biological products that are the subject of an approved application under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as of March 23, 2020, and will be deemed to be a biologics license application (BLA) under section 351 of the PHS Act on March 23, 2020.

Second, the FDA noted that it is reconsidering whether vaccines, which are currently within the scope of FDA's biologic naming framework, should be subject to the naming convention. The FDA mentioned that it will determine whether currently available identification systems are sufficiently robust to meet the FDA's pharmacovigilance goals.

Finally, for interchangeable biosimilar products to be approved in the future, the FDA intends to designate a proper name that is a combination of the core name[2], along with a distinguishing suffix that is devoid of meaning and composed of four lowercase letters. The FDA determined that a unique suffix would help determine which biological product is dispensed to patients when other means to track this information are not readily accessible or available. Use of the suffix will also avoid the need for changes to the nonproprietary name of a biological product that is first approved as a biosimilar product, and then later approved as an interchangeable product.

Ultimately, the unique suffixes in the FDA's proposed naming convention are a way for the FDA to better monitor adverse events and link them to a specific biologic product and manufacturer for patient safety. Comments and suggestions to the draft guidance should be submitted to the FDA by May 7, 2019.

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[1] "Proper Name" means the nonproprietary name designated by FDA in the license for a biological product licensed under the PHS Act (*see* 21 C.F.R. § 600.3(k)). The proper name generally reflects certain scientific characteristics of the product, such as chemical structure and pharmacological properties. This name is different from a proprietary name, which is generally a registered trademark.

[2] "Core Name" means the component shared among an originator biological product and any related biological product, biosimilar product, or interchangeable product as part of the proper

names of those products.