

COMMENTS SUBMITTED ON BEHALF OF THE BIOLOGICS LAW COMMITTEE FOR THE FOOD, DRUG AND COSMETIC LAW SECTION

On

U.S. Food and Drug Administration Guidance Entitled “Nonproprietary Naming of Biological Products: Update, Guidance for Industry”

Food, Drug and Cosmetic Law #3

May 2, 2019

As members of the New York State Bar Association Food, Drug and Cosmetic Law Section Biologics Law Committee (Committee), we are pleased to offer these comments on the U.S. Food and Drug Administration (FDA) Guidance entitled “Nonproprietary Naming of Biological Products: Guidance for Industry: Update” (“Guidance”) issued on March 2019.

Committee Purpose:

The purpose of the Committee is, in part, to keep the biologics and biosimilars industry and legal practitioners up to date and provide practical advice concerning issues that are of interest to the industry.

Such issues involve the FDA’s regulation of biological products, including its implementation of the Biologics Price Competition and Innovation Act (BPCIA) and related reimbursement and substitution rules, interactions with the FDA, Federal Trade Commission, and state agencies, and legislative developments. The Committee also follows the recent trends in litigation involving consumer class actions, labeling claims, biosimilars litigation, among others.

The Committee also seeks to engage members in programming and activities to contribute to the development of sound laws, policies, and regulations concerning the biologics industry, including biosimilars.

Committee Position:

On October 26, 2015, the Committee filed [Comments](#) in response to the “Nonproprietary Naming of Biological Products: Guidance for Industry” issued on August 28, 2015. As discussed in those Comments, the Committee agrees that a suffix will “avoid inaccurate perceptions of safety and effectiveness of biological products based on their licensure pathway.”¹ The Committee further agrees that there should be some distinguishing characteristic between initial biologic (351(a)), “biologic”), highly-similar biosimilar

¹ U.S. Food and Drug Administration, “Nonproprietary Naming of Biological Products: Guidance for Industry” (Aug. 28, 2015) at 1-2.

(351(k)(2)(A), “biosimilar”), and biosimilar interchangeable (351(k)(3),(4), “interchangeable”) products. Therefore, the Committee uses this comment period to identify issues involving the proposed naming scheme for the FDA’s consideration. We appreciate the FDA’s willingness to entertain these thoughts:

- We agree that a unique suffix should apply to reference products, biosimilar products, and interchangeable products for all of the reasons highlighted in the Guidance.
- The Committee continues to believe, as it did in 2015, that the suffix should convey a meaning, such as suggested in our Comments, particularly with respect to whether it is a biosimilar or an interchangeable. Even though biosimilars and interchangeable products will have different suffixes per the Guidance, there will be no easy way to identify which suffix represents a biosimilar as compared to an interchangeable based on the suffix alone. Perhaps prescribers and pharmacists will be able to memorize the suffixes in the short term, but as the number of biologics, biosimilars, and interchangeables continues to increase, a methodology will be needed to easily ascertain the intentions of the prescriber. Otherwise, the risk increases that the patient will receive the wrong drug.
- As discussed, in the Committee’s 2015 comment, not all biosimilars or interchangeables are equal in that a biosimilar may be licensed for only a subset of indications from the referenced biologic, and they may have a different route of administration. The ability to ascertain this information is difficult and time consuming, when the information is not readily available in the drug name or in the Purple Book and must be gleaned by comparing approved prescribing labelings.
- Contrary to the Guidance, the Committee believes that previously licensed biosimilars under section 351 of the Public Health Service Act (PHS Act) should receive a suffix. This will address a couple of concerns, namely:
 - Failure to apply the naming convention retroactively to previously-approved biological products will cause confusion in instances in which new biosimilars or interchangeables are approved for a reference drug that does not already have a suffix.
 - For example, if a new interchangeable is approved for a drug previously licensed under section 351 of the PHS Act, then the reference drug will not have a suffix, but the new interchangeable will have a suffix. When not all of the related products have a similar naming convention, it fails to “advance appropriate practices and perceptions regarding biological products,” which was a consideration identified in the “Nonproprietary Naming of Biological Products: Guidance for Industry.”² Failure to provide a

suffix to earlier biosimilars may create the public perception that they are different than other biosimilars/interchangeables. As stated in the Naming Guidance: “Applying this naming convention only for products licensed under section 351(k) of the PHS Act—but not for the reference product licensed under 351(a) of the PHS Act—could adversely affect health care provider and patient perceptions of these new products.” It is unclear to the Committee why this concern is not addressed consistently given that biosimilars and interchangeables can still be approved for these currently-approved, reference listed drugs.

- Failure to apply the naming convention retroactively can cause greater confusion for prescribers, pharmacists, and patients as to whether or not they are interchangeable. Unlike in the small molecule space, where branded and generic drugs can be readily substituted, this is not always possible in the biologic space. If the naming convention is designed to prevent that perception, then all drugs should be treated similarly. Otherwise, the naming convention only isolates these drugs from other biologics, creating the opinion that they are different in substance, rather than order of approval.

Conclusion:

Thank you for the opportunity to allow us to submit comments on this important issue. We welcome the opportunity to serve as a resource to you if you have further questions as you proceed further in your deliberating process.

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