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RE: Nonproprietary Naming of Biological Products: Update; Guidance for Industry (FDA-2013-D-1543-0213)

May 10, 2019

To Whom It May Concern:

The Biologics Price Competition and Innovation Act (BPCIA) established an approval pathway for products demonstrated to be biosimilar to or interchangeable with an FDA-licensed reference biologic. The BPCIA defines biosimilarity to mean that a product is "highly similar to the reference product" without "clinically meaningful differences" with regard to safety, purity, and potency of the product. For a product to be deemed "interchangeable," it must first meet the threshold showing of biosimilarity and also be expected to produce the same clinical result as the reference product in any given patient. Additionally, the risk in terms of safety or diminished efficacy of switching between the use of the interchangeable biosimilar and the reference product cannot be greater than the risk of using the reference product without switching.

The two main purposes of FDA's naming convention for biosimilars are pharmacovigilance and safe use. In January 2017, the agency released its naming guidance, which stated that all biological products would receive a "core" name with a unique four-letter suffix. This policy would apply to both innovator and biosimilar products.

In March 2019, the agency updated this guidance, stating that the four-letter suffix policy would now be applied prospectively. Thus, newly approved innovator, biosimilar, and interchangeable products would all receive a four-letter suffix, but biologics already on the market without suffixes would not.

We support this new application of the naming guidance. The sudden addition of a suffix for a biologic that has been marketed for years without one is confusing to clinicians, as it implies that something has changed about a well-known, older product. Eventually, as the market progresses towards newly approved biologics and biosimilars, products without suffixes will phase out.

Thank you for your consideration. Please do not hesitate to contact us, should you require additional information.

Sincerely,

Dr. Madelaine Feldman
President