JONES DAY

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COMMENTARY

FDA Indicates Shared Nonproprietary Names Not Appropriate for All Biological Products, Including Biosimilars

On August 28, 2015, the U.S. Food & Drug Administration ("FDA") released a draft guidance document describing its current position on biological product nonproprietary naming, including the need for biological products to bear a nonproprietary name to which is attached an FDA-designated suffix. The draft guidance represents FDA's latest efforts to address public comments received during its implementation of the Biologics Price Competition and Innovation Act of 2009, and it was issued on the same day as a separate but related proposed rule to designate official and proper names for six biological products under the same principles.

In determining that shared nonproprietary names are not appropriate for all biological products, FDA relied upon a need to improve pharmacovigilance and to aid the products' safe use by requiring more clearly differentiated naming of certain products. FDA intends the suffix differentiation to reduce inadvertent substitution, which may lead to unintended switching of products that have not been determined to be interchangeable, and to facilitate active pharmacovigilance. Consequently, as laid out in the draft guidance document, "Nonproprietary Naming of Biological Products," FDA states that each nonproprietary name designated for a biological product will include a unique suffix composed of four lowercase letters.

The naming convention would apply to newly and previously licensed biological products. It will consist of a "proper name"—the nonproprietary name designated by FDA in the biological product license—that will include a "core name" and a designated suffix. The "core name" is the "component shared among all related biological products as part of the proper name," using figrastim and epoetin alfa as examples of core names. For originator biologics, FDA intends to use the core name adopted by the United States Adopted Names ("USAN") Council. For those biological products that are related, biosimilar to, or interchangeable with the originator product, the core name will be the name of the drug substance in the relevant previously licensed product. To build out differentiation, FDA will add a four-letter suffix to the core name, attached with a hyphen. The core name is intended to indicate the relationship among products, while the suffix—four letters proposed by the sponsor but approved by FDA—will be used to distinguish among products.

At the appropriate time in development, FDA encourages applicants to propose suffixes that are

composed of four lowercase letters, unique, and devoid of meaning. The suffixes should not be promotional in nature, use abbreviations common to clinical practice, contain or suggest any drug substance name or core name, look similar to or be mistaken for the name of a currently marketed product, or be too similar to any other product's suffix designation.

In the draft guidance document, FDA made clear that it has not made a decision regarding the naming of interchangeable products. FDA continues to consider whether interchangeable products should share the suffix of the reference product or be unique.

FDA is requesting comments on the draft guidance and is specifically requesting input on ways to improve pharmacovigilance systems in monitoring biological product safety. Specifically, FDA would like feedback by **October 27, 2015**, on the following topics, among others:

- What are the potential benefits and challenges of designating a suffix in the proper name of a biological product that is devoid of meaning (versus meaningful) and unique to each biological product (versus unique to each license holder and shared by each biological product manufactured by that license holder)?
- What are the potential benefits and challenges for an interchangeable product to share the same suffix as designated in the proper name of the reference product?
- Would there be additional benefits or challenges if the suffix designated in the proper name of a biosimilar product that is subsequently determined to be interchangeable were changed to that of the reference product upon a determination of interchangeability? Would there be benefits or challenges to allowing the manufacturer of the biosimilar product that is subsequently determined to be interchangeable to have the option of retaining its original suffix or adopting the same suffix as the reference product?
- How could FDA and/or other federal partners improve active pharmacovigilance systems for purposes of monitoring the safety of biological products?
- What process and reasonable timeframe should FDA use to designate a suffix to include in the nonproprietary name of a previously licensed biological product?
- What criteria should FDA use to prioritize retrospective application of this naming convention to previously licensed biological products?
- What are the expected time frames for sponsors of previously licensed biological products to distribute products that conform to this naming convention after approval of a labeling supplement?
- What strategies could FDA use to enhance stakeholders' understanding of and education about this naming convention?

In a coordinated move, FDA also released a proposed rule to designate official and proper names for certain biological products to comport with the draft guidance document and to have the particular products add distinguishing suffixes composed of four lowercase letters. The six biological products addressed in the proposed rule were selected because they are either: (i) a reference product for an approved or publicly disclosed biosimilar application; (ii) a related biological product to one of the reference products; or (iii) a biosimilar product. While FDA continues to evaluate the appropriate naming convention—including how to apply it retrospectively—the Agency intends to act with respect to these six products through the proposed rule. FDA cites a need to encourage routine usage of designated suffixes in ordering, prescribing, dispensing, recordkeeping, and pharmacovigilance practices and to avoid inaccurate perceptions of safety and effectiveness based on how a product comes to be licensed as the basis for the action. FDA's proposed official and proper names for the six products, including a potential alternative on which the Agency is seeking comment, are as follows:

BLA	Current Name	Proposed official and proper name	Alternative official and proper name
103234	epoetin alfa	epoetin alfa-cgkn	epoetin alfa-amgn
103353	filgrastim	filgrastim-jcwp	filgrastim-amgn
125553	filgrastim-sndz	filgrastim-bflm	filgrastim-sndz
125294	tbo-filgrastim	filgrastim-vkzt	filgrastim-srbt
103772	infliximab	infliximab-hjmt	infliximab-jnsn
125031	pegfilgrastim	pegfilgrastim-ljfd	pegfilgrastim-amgn

FDA is accepting comments on the proposed rule by **November 12, 2015**.

Lawyer Contacts

If you would like to discuss how the draft guidance document or proposed rule may affect your current internal practices and procedures for naming, marketing, and developing distribution materials for your products, or if you are interested in our assistance in preparing comments to the draft guidance document or proposed rule, please feel free to contact your principal Firm representative or one of the lawyers listed below. General email messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com/contactus/.

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