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CLIENT ALERT

The Name Game – The FDA Issues Draft Guidance of Biologics Naming

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Shakespeare wrote, "***What's in a name***? That which we call a rose by any other name would smell as sweet." But Shakespeare certainly was not referring to the pharmaceutical marketplace, where drug product names play a critical role in healthcare delivery. Drug product names affect everything from how clinicians perceive the drug to how pharmacists dispense it, and how insurance plans pay for it. The ongoing debate is whether biosimilars, should have the same non-proprietary name as the original biologic, the "reference product," or whether they should have their own unique name. Arguments are made by the brand-name drug makers that a unique name for each biosimilar that distinguishes it from the reference product should be required as it would facilitate tracking adverse events and side effects in patient records. But the generic-drug makers argue that unique names for each biosimilar would confuse physicians and pharmacists wishing to make substitutions. Not only may a name impact the biologic's market share, the name may significantly impact prescribing, dispensing, and adverse event reporting and therefore patient safety as well as. Finally, after much lobbying by both brand and generic manufacturers, on Aug. 27, 2015 the U.S. Food and Drug Administration (FDA) released a long-awaited draft guidance document on the naming of biosimilars.

The FDA's draft guidance proposes that reference products and biosimilars have nonproprietary names that share a "core drug substance" name but also include an FDA-designated suffix that is unique for each product. This suffix would be composed of four lowercase letters and would be devoid of any meaning. For originator biological products, FDA intends to use a core name that is the name adopted by the U.S. Adopted Names (USAN) Council for the drug substance when available. If the biological product is a related, biosimilar, or interchangeable product, the core name will be the name of the drug substance contained in the relevant previously licensed product. The core name will indicate a relationship among products and the use of the core name and suffix will facilitate use of the FDA's *Purple Book: Lists of Licensed Biological Products With Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*." The FDA specifically requests feedback from the public about whether the nonproprietary name for an interchangeable product should include a distinct suffix, or should share the same suffix as its reference product.

The FDA's draft guidance offers a compromise, a naming convention that maximizing the success of biosimilar products and interchangeable products, while ensuring the safety of patients receiving biological products licensed under the Public Health Service (PHS) Act.

The FDA's stated intent is to clearly identify biological products to improve pharmacovigilance and, for the purposes of safe use, differentiate among biological products that have not been determined to be an "interchangeable" product. An interchangeable product can be expected to produce the same clinical result as the reference biological product in any given patient and additionally may be substituted for the reference product by a pharmacist without the intervention of the prescribing health care provider (see section 351(i)(3) of the PHS Act). By differentiating among biological products that have not been determined to be interchangeable, the FDA's goal is to help minimize inadvertent substitution, which may lead to unintended alternating or switching of biological products that are not interchangeable. Furthermore, the naming convention would be applicable both to

biological products previously licensed and newly licensed under sections 351(a) and 351(k) of the PHS Act. The FDA states that applying the naming convention to all biological products will (1) encourage routine use of designated suffixes in ordering, prescribing, dispensing, and record-keeping practices and (2) avoid inaccurate perceptions of the safety and effectiveness of biological products based on their licensure pathway.

At present, the FDA is also proposing a regulation to designate official names and proper names for a small group of biological products that follows this naming convention: These products are filgrastim-sndz (Biologics License Application (BLA) 125553), filgrastim (BLA 103353), tbo-filgrastim (BLA 125294), pegfilgrastim (BLA 125031), epoetin alfa (BLA 103234), and infliximab (BLA 103772). The official names and proper names of these products would include distinguishing suffixes composed of four lowercase letters and would be filgrastim-bflm (BLA 125553), filgrastim-jcwp (BLA 103353), filgrastim-vkzt (BLA 125294), pegfilgrastim-ljfd (BLA 125031), epoetin alfa-cgkn (BLA 103234), and infliximab-hjmt (BLA 103772).

The proposed naming convention would apply to all biological products, but the FDA is considering two approaches when it comes to naming interchangeables: (1) names distinct from the reference product where the interchangeable has a unique suffix of four lowercase letters for use as the distinguishing identifier included in the proper name designated by FDA, or (2) names shared with the reference product where the interchangeable product and the reference product would have the same core name and suffix.

The FDA specifically requests feedback from the public about whether the nonproprietary name for an interchangeable product should include a distinct suffix, or should share the same suffix as its reference product. To ensure your comments on the draft guidance are considered by the FDA before it begins work on the final version of the guidance, the agency requests comments be submitted before October 27, 2015. Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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