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# FDA Issues Draft Guidance and Proposed Rule on the Nonproprietary Naming of Biological Products

On August 28, 2015, FDA issued a draft guidance document and a proposed rule addressing the nonproprietary naming of biological products. Because nonproprietary naming can have substantial effects on the market for biosimilar products, this much-anticipated action is likely to attract significant comment from stakeholders.

In the draft guidance, *Nonproprietary Naming of Biological Products*, FDA proposes to designate a nonproprietary name for biological products that includes a suffix composed of four lowercase letters. FDA proposes to apply this convention to all biological products licensed under sections 351(a) and 351(k) of the Public Health Service Act ("PHSA"), as added by the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). The accompanying proposed rule would apply FDA's proposed naming policy to six biological products previously licensed under the BPCIA.

According to FDA, the proposed naming convention serves three primary goals: (1) preventing the inadvertent substitution of biological products not determined to be interchangeable by FDA, which could lead to medication errors; (2) enhancing manufacturer-specific pharmacovigilance of biological products on the market, by facilitating the tracking of their usage and any adverse events across care settings, including outpatient, hospital, and pharmacy settings; and (3) providing a consistent, readily available and recognizable mechanism for patients and health care professionals to correctly identify biological products so as to advance accurate perceptions of biological products.

## Proposed Naming Convention: Core Name + Suffix

The draft guidance proposes a naming convention that includes a core name and a designated suffix (together, a "proper name"). For originator products, FDA proposes to use a core name adopted by the United States Adopted Names (USAN) Council for the drug substance when available. If the biological product is a related biological product, a biosimilar product, or an interchangeable product, the core name will be the name of the drug substance contained in the relevant previously licensed product.

A designated suffix composed of four lowercase letters will be added to the core name of each product and will be attached with a hyphen. FDA states that the placement of the identifier as a suffix, rather than a prefix, would result in biological products with the same core name being grouped together in electronic databases to help health care providers identify related products.

## Proposed Naming of Interchangeable Products

The guidance also states that FDA intends to apply the naming convention to interchangeable biological products and is considering two alternative approaches: 1) a unique suffix that distinguishes an interchangeable product from other products sharing the same core name; and 2) a suffix shared with the reference product.

FDA intends to apply the core name + suffix naming convention to biological products previously licensed under section 351 in addition to newly licensed products. In the near term, however, FDA will be assigning distinguishing suffixes through rulemaking to a limited group of biological products that are referenced by approved or publicly announced pending biosimilar applications and any products related to those reference products.

## Manufacturer's Proposed Suffix

The draft guidance specifies that applicants for biological products submitted both under 351(a) and 351(k) should propose a suffix for use as the distinguishing identifier; no more than three suffixes can be submitted. The suffix should be unique, devoid of meaning, and consist of four lowercase letters. The suffix should not be promotional, include abbreviations commonly used in clinical practice, contain or suggest any drug substance name, look similar to a currently marketed product, or be too similar to any other product's suffix designation.

While the draft guidance describes a naming convention in which the designated suffixes would be devoid of meaning as described above, the notice of availability for the draft guidance invites comments not only on that naming convention but also on the benefits and challenges of alternate approaches. Such alternate approaches include meaningful suffixes such as a suffix derived from the name of the license holder.

## The Proposed Rule

In the related proposed rule, FDA designates nonproprietary names for six previously licensed biological products, each of which is either a reference product for an approved or publicly disclosed biosimilar product application or a biological product that is biosimilar to or related to one of those reference products. The official names of the products proposed by FDA would include distinguishing suffixes devoid of any meaning composed of four lowercase letters, such as "filgrastim-bflm," "epoetin alfa-cgkn," and "infliximab-hjmt." According to the proposed rule, FDA is also considering an alternative format in which the suffix would be derived from the name of the license holder, such as "epoetin alpha-amgn" (for license holder Amgen) and "filgrastim-sndz" (for license holder Sandoz, Inc.).

FDA has encouraged the public to provide input on both the proposed rule and draft guidance. Comments on the guidance may be submitted by October 27, 2015, and comments on the proposed rule should be submitted by November 12, 2015. FDA is particularly interested in comments on (1) the benefits and challenges of designating a unique suffix versus a distinguishing suffix shared by products manufactured by a single license holder, (2) whether meaningful suffixes would be expected to be more memorable to health care providers/patients and therefore more useful for facilitating safe use and appropriate pharmacovigilance, and (3) whether meaningful suffixes derived from the name of the license holder might create inappropriate market advantages that would impede biosimilar products' acceptance in the market.

Although the proposed rule and guidance shed some light on FDA's likely approach toward the naming of biological products, the mechanics of the final naming convention remains somewhat uncertain as the guidance seeks extensive input from stakeholders. Furthermore, neither the guidance nor the rule addresses the process and timeframe FDA will use to designate suffixes in the nonproprietary names of previously licensed products, the criteria FDA will use to prioritize the retrospective application of the proposed naming convention to previously licensed biological products, or the expected time frame for sponsors of previously licensed biological products to distribute products that conform to the naming convention after approval of a labeling supplement.