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# FDA Maintains Assigned Unique Suffixes in Generic Names for Biologics

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On January 12, 2017, the FDA issued its final guidance on generic naming for biological products submitted pursuant to 351(a) or (k) of the Public Health Service Act. The guidance is titled ***Nonproprietary Naming for Biological Products*** and maintains the FDA's proposal set forth in its previous draft guidance issued in August 2015.

## Naming convention

Under the FDA's final naming convention, the nonproprietary name ("proper name") for each biological product must consist of a "core name" that reflects the product's scientific traits, which will be separated by a hyphen from a suffix that is devoid of meaning. The core name, which will consist of the United States Adopted Name, will be the same for all products that share the relevant biological substance (originator, related, biosimilar or interchangeable) in order to indicate a relationship among the products. By contrast, the FDA-assigned suffix will be comprised of four lowercase letters and unique to each product.

For example, the following proper names may be displayed for products that share a relationship with a common biological substance:

| | Product 1 | Product 2 |
|---|---|---|
| Products sharing core name replicamab | replicamab-cznm | replicamab-hjxf |
| Products sharing core name putonastim alfa | putonastim alfa-jnzt | putonastim alfa-kngx |

Although the FDA will designate the suffix to be incorporated into the proper name, applicants (and current BLA holders) are permitted to submit up to 10 proposed suffixes for the agency's consideration. The proposed suffixes must satisfy certain requirements such as the inclusion of at least three distinct letters and avoiding similarity to the applicant's name.

## Debate and comments

Among its reasons for adopting the unique suffix naming convention, the FDA cited enhancing pharmacovigilance, reducing confusion and inadvertent substitution, and avoiding inaccurate public perceptions. During the prior public comment period, industry groups, healthcare practitioners and biologics innovators also cited similar reasons to support the use of distinguishable suffixes.

On the other hand, biosimilars manufacturers and insurers had opposed the use of distinguishable suffixes. They argued that since proper names reflect pharmacological characteristics, different suffixes may imply that biosimilars have meaningful clinical differences from the reference product, and thus their use would create barriers to competition and stigmatization that could hinder

uptake.

## Key open issue

One key issue that the FDA did not address in its final guidance concerns the naming convention for interchangeables. That issue will be addressed following further consideration by the agency.