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The *fix* for biosimilar suffix development

Legislation passed in the last decade encourages pharmaceutical companies to invest more in development of biosimilar products.

With any drug development, there are strict regulatory guidelines to be aware of. As it relates to naming, biologics and biosimilars are required to go through the same stringent approval process as their synthetically manufactured counterparts but what about their naming guidance is different?

Answer: Per FDA naming guidance for non-proprietary names, any biologic or biosimilar medication is now required to include a randomized four-letter suffix.

drugname-wxyz

But why? What purpose will these suffixes serve?

What is a biosimilar?

According to FDA.gov, biosimilars are a type of biological product that are approved because they are highly similar to an already FDA-approved biological product and have been shown to have no clinically meaningful differences from the reference product.

The Biologics Price Competition and Innovation Act “established an abbreviated licensure pathway for products demonstrated to be biosimilar to or interchangeable with an FDA-licensed reference product.” The establishment of a licensing fast track means that companies are increasingly shifting their focus to producing these products. As more companies pursue the biosimilar pathway, the need for non-proprietary naming guidelines specific to biosimilars has emerged (Non-proprietary 2017).

According to the FDA, these suffixes “can serve as a key element to identify specific products in spontaneous adverse event reporting and to reinforce accurate product identification in billing and claims records used for active pharmacovigilance,” and the distinguishing suffixes are to counteract the “inadvertent substitution” between biologics and biosimilars.

There are two opportunities for suffix naming: prospective naming and retrospective naming. Here’s what you need to know for both:

Prospective naming

During prospective naming, applicants should propose a suffix composed of four lowercase letters during the investigational new drug application (IND) phase or at the time of Biologics License Application (BLA) submission. Submission of up to 10 proposed suffixes is allowed and supporting analyses should be included for the FDA’s consideration.

Retrospective naming

Retrospective naming occurs when the non-proprietary name has already been established but must now be modified to comply with current guidance. A BLA holder may propose a suffix for use in the proper name of currently licensed biological products held by the company by submitting a prior-approval labeling supplement to its BLA. Again, submission of up to 10 proposed suffixes is allowed with supporting analyses.

The request seems simple enough, doesn’t it? Create a randomized string of four letters. It might seem that way until you delve into the complex realm of the regulatory landscape.

Finding four-letter strings that are devoid of meaning is more challenging when you take into account the plethora of USAN stems, medical abbreviations, dosing instructions, and slang terminology cluttering our environments these days.

Be four lowercase letters of which at least three are distinct

Be free of legal barriers that would restrict its usage

Don’t include abbreviations

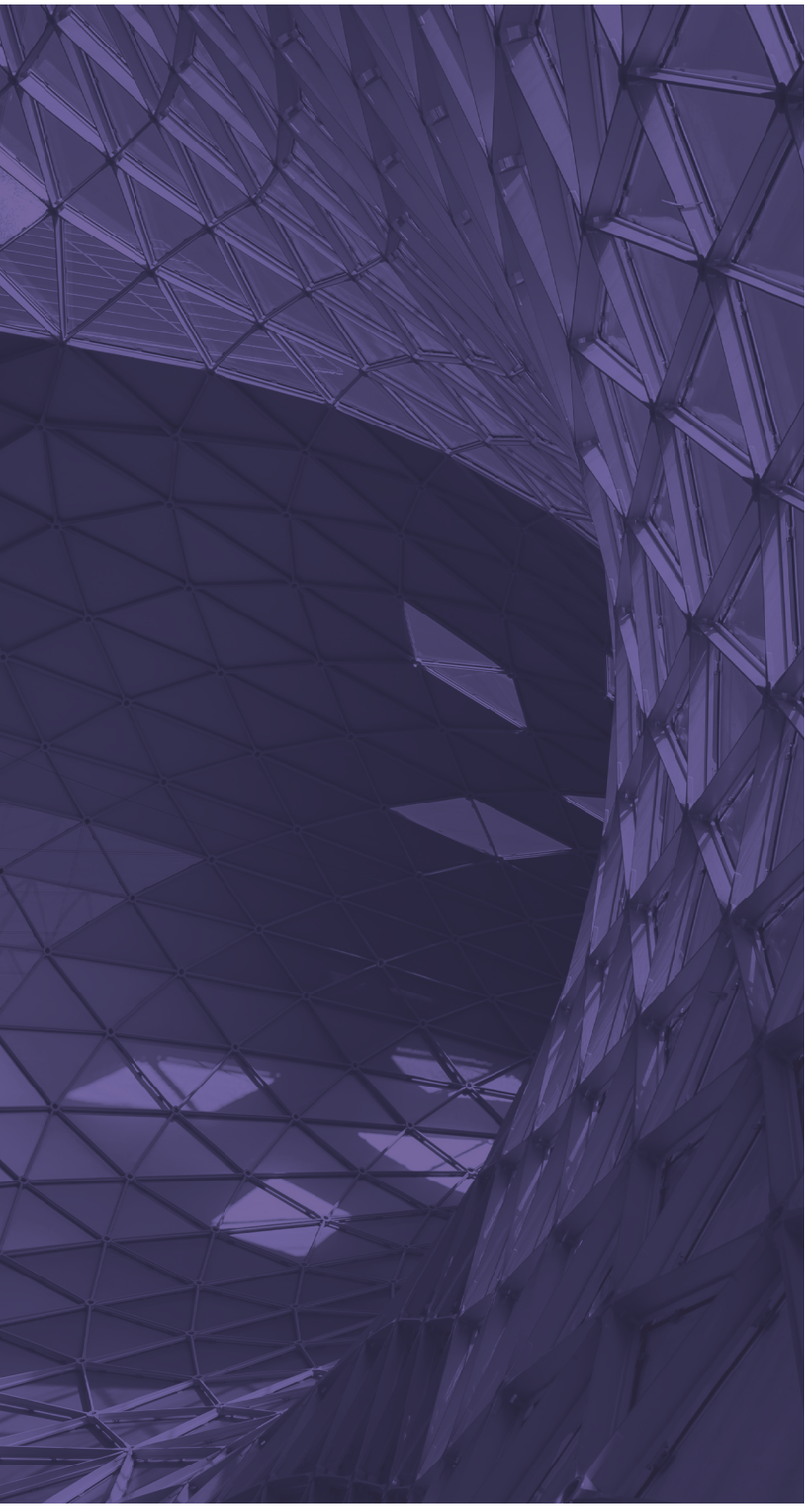
Be unique

Don’t look similar to or be capable of being mistaken for the name of a currently marketed product

Don’t be false or misleading

Be devoid of meaning

Consider safety or efficacy

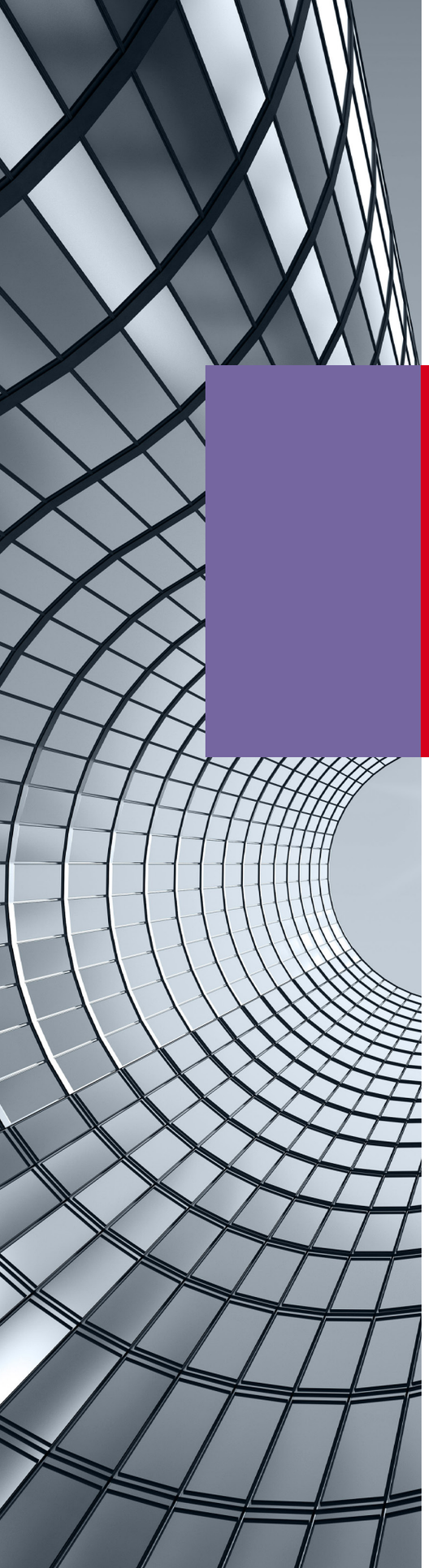


While biologic suffix development may not seem like a difficult task, submissions can be easily rejected if the guidance is not followed and supporting documentation is not provided. To ensure compliance, streamline the submission process, and gain a strategic advantage, companies should seek assistance from agencies that have extensive expertise in naming and regulatory guidelines.

Addison Whitney has implemented an in-depth, strategic process to ensure regulatory compliance. By employing our rigorous global prescreening and safety checks, companies can often avoid rejection due to medical or negative connotations.

Did you know?
One essential step is to ensure there are no USAN stems embedded within the suffix. Since stems are assigned based on specific structural and chemical compositions, using one inappropriately can and will be a cause for rejection.

As biologic suffixes are fairly new to market and regulatory agencies, changes to the guidance can and should be expected. As a professional branding firm, Addison Whitney is committed to staying up-to-date on guidance and making strategic naming its key focus.



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Gaining regulatory approval is hard.

And for every delay you encounter you are losing millions of dollars, which is why guidance through the complex regulatory landscape of drug naming demands a smart strategy.

Contact us today to get started on your naming and submission strategy.

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