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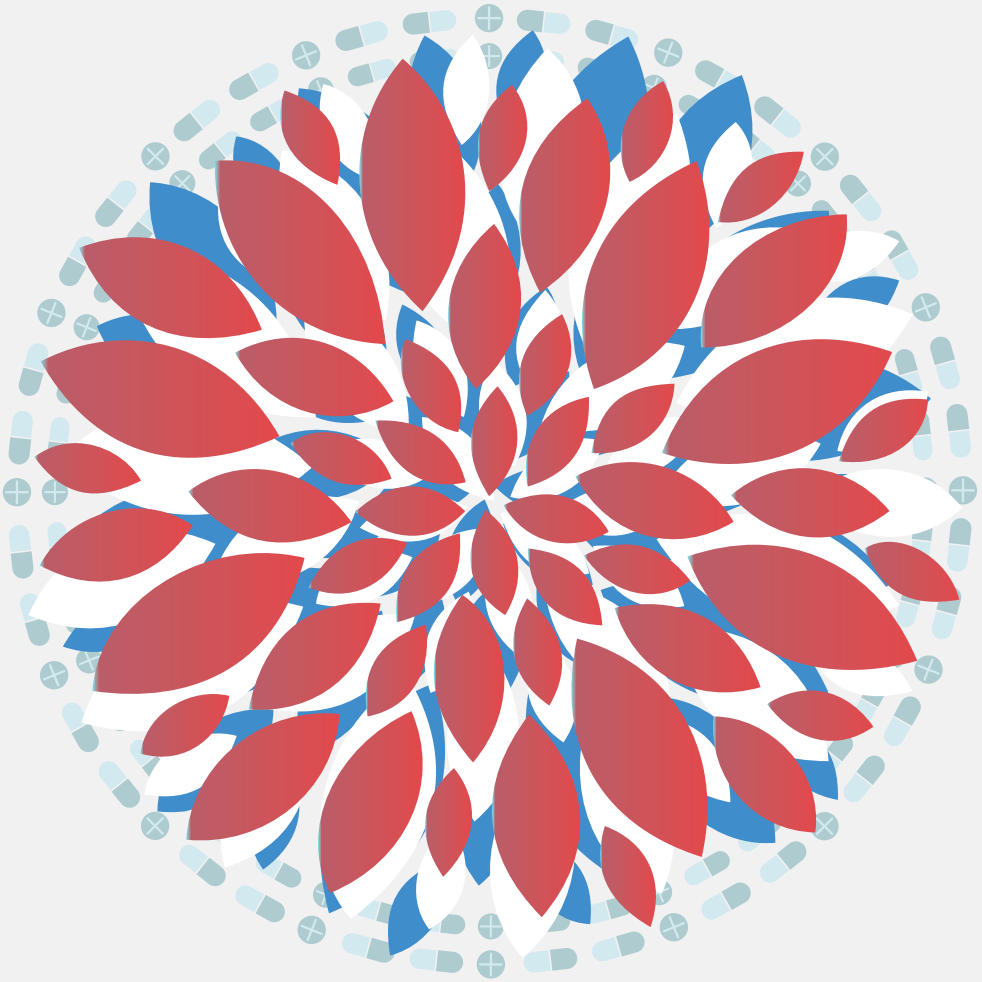

UNITED STATES BIOPHARMACEUTICALS

2017

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Biosimilars – An Update on Recent FDA Industry Guidance

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Biosimilars are a type of biological product (e.g. therapeutic antibodies) highly similar to an already approved biological reference listed product (RLD). While biosimilars are highly similar to a RLD, they are not exactly the same and some physician concerns exist regarding the potential for patients to respond differently to a biosimilar than the RLD in certain contexts. For this reason, a pharmacist cannot simply substitute a biosimilar for an RLD without instruction from a prescribing physician. However, if the FDA determines that a biosimilar is "interchangeable", then in addition to being highly similar to an RLD, it is expected to produce the same clinical result as the reference product in any given patient. A pharmacist can substitute such a product for the RLD without additional physician approval.

Guidance on Demonstrating Biosimilar Interchangeability

In January of 2017, the FDA issued a draft guidance regarding demonstrating interchangeability with a reference product. This guidance is important because it provides insight into what type of data the FDA will want to consider for this inquiry: "The data and information to support a showing that the proposed interchangeable product can be expected to produce the same clinical result as the reference product in all of the reference product's licensed conditions of use may vary depending on the nature of the proposed interchangeable product". This may include analysis of differences between the RLD and proposed interchangeable product, immunogenicity issues, pharmacokinetics and toxicity issues. The FDA advises industry sponsors intending to develop a proposed interchangeable product to consult with the FDA early in the process regarding development plans, scientific justifications and potential data submissions to streamline the process.

Switching studies appear to be a key piece of information considered by the FDA in interchangeability inquiries. "The main purpose of a switching study or studies is to demonstrate that the risk in terms of safety or diminished efficacy of alternating or switching between use of the proposed interchangeable product and the reference product is not greater than the risk of using the reference product without such alternation or switch." Depending on the complexity of the biologic at issue, the FDA may also require additional data from post marketing studies of a biosimilar before granting interchangeability status.

Overall while more clarity regarding exact requirements is to be desired, this draft guidance is an important document providing insight into what the FDA is looking for.

FDA Guidance on Biosimilar Naming and Labeling

Last year, the FDA also issued a draft guidance regarding biosimilar labeling. The FDA recommended labels contain a statement that a product is biosimilar to a RLD. However, it did not require an interchangeability statement (e.g. a non-interchangeable biosimilar does not have to disclose in its label that it is not interchangeable). This caused some controversy. Some organizations opined that a label should contain a statement about whether or not a biosimilar is interchangeable. They argued that this would help avoid a situation, for example, where a physician mistakenly believes that a biosimilar is interchangeable (some physicians only consult the label before prescribing).On the other hand, other organizations opine that the interchangeability statement is unnecessary and could artificially decrease physician preference for prescribing a biosimilar. We will see how this is dealt with in the FDA's final guidance.

In January of this year, the FDA issued a final guidance on biosimilar naming. In addition to a core name, a four character suffix is also required (e.g. filgrastim-sndz). This will help avoid any confusion regarding origins of a biologic.