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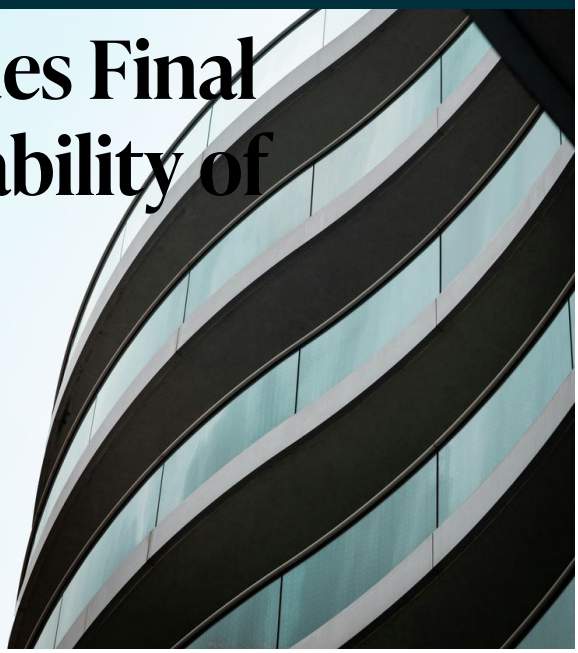
Axinn IP Update: FDA Issues Final Guidance on Interchangeability of Biologics



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Axinn Update

On May 9, 2019, FDA released its final guidance regarding the interchangeability of follow-on biologic products with their branded counterparts. Although the final guidance clarifies a few details of FDA's approval requirements, there was one major change from the draft guidance previously issued by FDA regarding when it is appropriate to use non-U.S.-licensed reference products. The remainder of the guidance was relatively the same as the draft. The final guidance reinforces that interchangeable follow-on products must meet the same standards as biosimilar follow-on products: they must be highly similar to the reference product, with no clinically meaningful differences as to safety, purity, or potency.

In a major change between the draft and final guidance, FDA eases up on the draft guidance's admonition to not compare the sponsor's product to a non-U.S.-licensed reference product. In the final guidance, FDA states that it may allow such comparisons if the sponsor establishes a "bridge" between the U.S.-licensed and non-U.S.-licensed reference products based on "adequate data and information." It remains to be seen if such comparisons will be successful.

Although the final guidance sets forth a role for postmarketing surveillance of biosimilar follow-on products, FDA makes clear that postmarketing surveillance alone is not sufficient to support interchangeability. Thus, FDA maintains that – in addition to data supporting a finding that it is "highly similar" – switching studies, designed with a minimum of three switches, are required for a follow-on biologic to be approved as interchangeable with the reference product.

Interestingly, the guidance implies that advances in analytics may later obviate the need for switching studies, but leaves no doubt that – for the time being – FDA expects switching studies will be required before a follow-on biologic can be approved as an interchangeable. FDA does not state what such analytical advances might be, but it suggests that they may lead to more selective and targeted approaches to clinical studies that will support a demonstration of interchangeability.

The final guidance additionally confirms that follow-on biologic sponsors may be able to extrapolate data from switching studies to achieve interchangeable status for additional conditions of use for which the reference product is licensed. FDA states that sponsors should address the biologic's mechanism of action and differences in patient populations that may affect the product's pharmacokinetics, bioavailability, immunogenicity, and toxicity when extrapolating data.

FDA's final guidance can be accessed here.

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