

## FDA Issues Final Guidance on “Labeling for Biosimilar Products”

The FDA’s final “Labeling for Biosimilar Products Guidance for Industry” (Final Guidelines) should be viewed as a clear effort to boost timely access to biosimilars, drive down costs of existing biologics, and increase competition without pushing too hard against reference drug providers. The Final Guidelines focus on the prescribing information (i.e., the package insert), but briefly address FDA approved patient labeling. On the one hand, the FDA’s guidance aligns with the labeling policy for generic pharmaceutical products by permitting the labels for biosimilars to be very similar to the drugs they reference. For example, biosimilar labels do not need to include any statement that the biosimilar product was approved based on less data than the reference drug or descriptions from clinical biosimilarity studies. However, the FDA’s guidance distinguishes labeling for biosimilars from generic pharmaceutical products by requiring biosimilar labeling to include a biosimilarity statement.<sup>1</sup>

The remainder of this alert outlines the FDA’s position on when and where biosimilar labeling must differ from the reference product, where the guidelines are silent, and summarizes how the Final Guidelines are consistent with the FDA’s latest efforts to expand the biosimilars market through its “Biosimilars Action Plan.”

### Labeling Requirements Specific to Biosimilar Products:

- Any information specific to the biosimilar product must be included in the label such as information on “administration, preparation, storage, or safety information.”
- Biosimilar labeling must meet the requirements of the pregnancy and lactation labeling final rule (21 C.F.R. § 201.57(c)(9)(i)-(iii)) and the physician labeling rule (21 C.F.R. §§ 201.56(c)(1), (d), and 201.57), regardless of whether the reference product labeling must satisfy such requirements.
- The labeling should specify either the biosimilar product’s proprietary or proper name for “text that is specific to the biosimilar product or that refers solely to the biosimilar product” and text that refers to “preventing, monitoring, managing, or mitigating risks.” Furthermore, the biosimilar product’s proper name should be listed when referencing the drug substance such as in the DESCRIPTION section of the label.<sup>2</sup>
- If a biosimilar product will be licensed for “fewer than all conditions of use (e.g., indication(s), dosing regimen(s)) for which the reference product is licensed,” language specific to these other conditions of use should typically be excluded from the biosimilar label. However, these other conditions of use may be required to be included “in order to help ensure safe use (e.g., when safety information in the reference product labeling is related to use of the product and is not specific to a particular licensed indication(s) or when information specific to only the biosimilar product’s indication(s) cannot be easily extracted).”<sup>3</sup>
- The initial U.S. approval in the “Highlights” section of the biosimilar label should list the year that the biosimilar product was licensed.
- FDA Approved Patient Labeling:
  - If a Medication Guide is required pursuant to 21 C.F.R. § 208, applicants must comply with the Medication Guide regulations pertaining to biosimilar product labeling. If the reference product includes Patient Information, applicants should modify this information to apply to the biosimilar product.
  - If the FDA approved patient labeling for the reference product contains Instructions for Use, this information should be modified for the biosimilar product labeling if, “for example, modified language or images are needed to describe the biosimilar product accurately.”<sup>4</sup>



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### Related Practice Areas

- Biologics/Biosimilars
- Health Care
- Intellectual Property

Although the Final Guidelines expressly mention interchangeable products, the FDA only states that any recommendations for such products “will be provided in the future.”

Overall, these Final Guidelines are consistent with the FDA’s goal to show biosimilarity between a proposed product and its reference product without requiring the applicants for the proposed product to independently establish safety or effectiveness of the proposed product. The Final Guidelines are another step by the FDA towards achieving FDA Commissioner Scott Gottlieb’s three-pronged Drug Competition Action Plan that encourages competition and helps bring greater efficiency and transparency to the process. We anticipate that new guidance and communications regarding the Drug Competition Action Plan will be released by the FDA before the end of the year and will continue to monitor and provide updates.

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**To discuss any questions you may have regarding the issues discussed in this Alert please contact Alanna Miller at (212) 883-2238 or [amiller@cozen.com](mailto:amiller@cozen.com), Ryan Blaney at (202) 463-2528 or [rblaney@cozen.com](mailto:rblaney@cozen.com), or Blake Coblentz at (202) 912-4837 or [wcoblentz@cozen.com](mailto:wcoblentz@cozen.com).**

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<sup>1</sup> The biosimilar statement must be placed on the line immediately beneath the initial U.S. approval in the Highlights section and state: “[BIOSIMILAR PRODUCT’S PROPRIETARY NAME (biosimilar product’s proper name)] is biosimilar\* to [REFERENCE PRODUCT’S PROPRIETARY NAME (reference product’s proper name)].” The asterisk after “biosimilar” should be a footnote symbol.

<sup>2</sup> See Section IV (A) for more specific examples of when to list the biosimilar product’s proprietary or proper name and further discussion of when to use the reference product name or core name.

<sup>3</sup> See Section IV (B) for more detailed explanation and demonstrative example.

<sup>4</sup> See Section V for further guidance on proposed changes to the biosimilar label based on changes to the product itself.