FDA Issues Draft Guidance on Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products

Alan G. Minsk and Genevieve M. Razick

On February 3, 2020, the Food and Drug Administration's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research issued jointly a draft guidance entitled, "Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products – Questions and Answers."[1] In announcing the draft guidance, FDA said that, with the passage of the Biologics Price Competition and Innovation Act (BPCIA) of 2009, it "expects an increase in promotion involving reference products and biosimilar products."[2]

Anyone can submit comments on the draft guidance to the agency by April 6, 2020. However, FDA specifically seeks input on the following questions:

- What are the unique promotional considerations for interchangeable biosimilars, if any?
- What other considerations can help promotional materials provide truthful and non-misleading information about interchangeable products to different audiences, such as patients and healthcare providers?

We will not discuss biosimilar or interchangeable products in this Bulletin.

Highlights of the Draft Guidance

The draft guidance covers promotional issues involving both reference and biosimilar products, but does not discuss issues that are unique to promotional materials for interchangeable biosimilars.

Truthful & Non-Misleading

Promotional materials for reference products and biosimilar products, similar to prescription drugs, must:

- be truthful and non-misleading
  - this is a "fact-specific determination," which should consider how the information is presented, the type and quality of the data relied upon to support the presentation, and contextual and disclosure factors
  - the company must revise the biological product promotional labeling and advertising for certain labeling changes, particularly those relating to risk information
- provide information about a product's efficacy and its risks in a balanced manner (i.e., fair balance)
- discuss material facts about the products

There is also the "truthful in isolation, but misleading in context" scenario we have discussed with

1 See www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp

2 85 Fed. Reg. 6201 (Feb. 4, 2020). The BPCIA, amending the Public Health Service Act, provides an abbreviated licensure regulatory pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference product.

clients and mentioned in webinars. That is, something can be factually accurate but, in context, misleading. The agency provides an example of a presentation in promotional materials for a reference product, which compares the number of indications for which the reference product is licensed to the number of indications for which the biosimilar is licensed in a manner "that creates the net impression that the biosimilar product is in general less safe or less effective than the reference product simply because the biosimilar is licensed for fewer indications than the reference product."

Naming Conventions

In promotional materials, reference and biosimilar products may identify themselves by their proprietary name, nonproprietary or proper name, or core name.[3]

- The context will decide which naming convention is most appropriate.
- According to the draft guidance, "if a biosimilar product's FDA-approved labeling uses the core name of the reference product followed by the word 'products' to convey that a risk applies to both the biosimilar and the reference product, it would also be appropriate for similar presentations about this risk in promotional materials for the biosimilar to use this nomenclature"

Referencing the Label

The agency recommends that companies intending to develop promotional materials that include information from studies conducted to support licensure of the reference product, which are included in both the reference product and biosimilar's FDA-approved labeling, should refer to the biosimilar product's FDA-approved labeling.

- In other guidance, the agency has advised that a biosimilar product's FDA-approved labeling provide relevant data and information from the reference product's FDA-approved labeling, including clinical data that supported the agency's finding of safety and effectiveness of the reference product.
    - E.g., if a biosimilar product is licensed for fewer than all conditions of use for which the reference product is licensed, the biosimilar's FDA-approved labeling generally contains the data and information from the reference product's FDA-approved labeling that is relevant to the licensed conditions of use of the biosimilar product.

Companies that provide biosimilar promotional materials, which include data and information from studies that were conducted to support a demonstration of biosimilarity between the biosimilar product and the reference product but that are not included in the biosimilar product's FDA-approved labeling, must ensure they are consistent with the biosimilar's FDA-approved labeling and must be truthful and non-misleading. See *Medical Product Commications That Are Consistent With the FDA-Required Labeling – Questions and Answers (June 2018)*.[4]

Comparative Claims

Firms must be careful about comparative claims between reference and biosimilar products in promotional materials.

- FDA recommends that firms "avoid presentations that represent or suggest that a licensed biosimilar is not highly similar to the reference product or that a clinically meaningful difference in terms of safety, purity, or potency exists between the reference product and biosimilar."

3 A biological product's proprietary name means the trademark or brand name. The proper name is the nonproprietary name, designated by FDA in the product's license. The core name is the component shared among a reference product and any related biological product, biosimilar product, or interchangeable product as part of the proper names of those products.

4 See AGG Bulletin available at https://www.agg.com/news-insights/publications/talk-this-way-pt-2-07-11-2018/

It is misleading to suggest that a biosimilar product is superior to its reference product based on a difference that is not clinically meaningful between the rates of occurrence of a particular adverse reaction from a study that supported a demonstration of biosimilarity between the reference product and biosimilar; similarly, it is misleading to suggest that the reference product is less safe or less effective than its biosimilar based on that study.

A biosimilar product should not claim to be interchangeable with the reference product if FDA has not made that determination; similarly, a reference product should not promote that a biosimilar product is less safe or effective because it has not been licensed as interchangeable with the reference product.

Because a biosimilar product is not required to be identical to the reference product, it is not accurate for a biosimilar product to suggest that FDA determined they are identical to one another; conversely, a reference product should not represent the licensed biosimilar is not as safe and effective as the reference product because it may not be identical to the reference product.

Pre- and Post-Marketing Considerations

Companies may ask FDA for feedback on promotional materials for reference or biosimilar products prior to dissemination.

Firms must comply with FDA's postmarketing reporting requirements for submitting promotional materials to the agency (i.e., Form FDA 2253 submissions for prescription drugs and biologics).

FDA regulations also require that companies promptly revise promotional labeling and advertising for their biological products upon certain labeling changes (e.g., changes to risk information).

AGG Observations

- The draft guidance, while not legally binding, provides FDA's current thinking on a relatively new area of product promotion -- biological reference and biosimilar products.
- The guidance is not too dissimilar from recommendations that would normally be made for prescription drugs (e.g., truthful, non-misleading). However, because of the nuances of biosimilars, there are some specific discussion points that are worthy of review.
- Similar to prescription drug promotion, context and the entire presentation of information matters, as FDA reiterates.
- A company that intends to promote biological reference or biosimilar products should review the draft and, if it has questions or concerns, it should submit comments by the April 6 deadline.

Authors and Contributors

Alan G. Minsk
Partner, Atlanta Office
404.873.8690
alan.minsk@agg.com

Genevieve M. Razick
Associate, Atlanta Office
404.873.8196
genevieve.razick@agg.com

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