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Client Alert

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FDA Releases Draft Guidance on Promotion of Biological Reference and Biosimilar Products

Part of a New Joint Initiative with FTC to Deter Anti-Competitive Practices, Including False or Misleading Comparisons

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On February 3, 2020, the U.S. Food and Drug Administration ("FDA") released draft guidance providing recommendations for promotional materials for biological reference and biosimilar products, titled *Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products: Questions and Answers* ("draft guidance").[1] The draft guidance is part of a new joint effort with the Federal Trade Commission ("FTC") to support market competition for biologics, including the adoption of biosimilars products.[2]

BACKGROUND

In July 2018, FDA published a dynamic Biosimilars Action Plan[3], with four key elements and priority deliverables focused on:

1. Improving the efficiency of the biosimilar and interchangeable product development and approval process.

2. Maximizing scientific and regulatory clarity for the biosimilar product development community.

3. Developing effective communications to improve understanding of biosimilars among patients, clinicians, and payors.

4. Supporting market competition by reducing gaming of FDA requirements or other attempts to unfairly delay competition.

Key deliverables for the fourth element included coordinating with the FTC to address anti-competitive behavior, which culminated in a newly announced joint collaboration to support appropriate adoption of

biosimilars, deter false or misleading statements about biosimilars, and deter anti-competitive behaviors in the biological product industry. In furtherance of this effort, the FDA and FTC identified four goals – among them, their intention "to take appropriate action against false or misleading communications about biologics, including biosimilars, within their respective authorities" under the Food, Drug, and Cosmetic Act and the Federal Trade Commission Act.4

This issuance of the new draft guidance by FDA is a key part of the joint goal set by the FDA and FTC. It is also a partial response to a Citizen Petition filed in 2018 requesting that FDA "issue guidance to ensure truthful and non-misleading communications by sponsors concerning the safety and effectiveness of biosimilars, including interchangeable products, relative to reference product(s)."[5] The need for guidance underscores the growing tensions between companies marketing reference biologics and companies marketing biosimilar products.

KEY TAKEAWAYS

Recommendations in the draft guidance are rooted in the fundamental requirement that promotional materials for reference and biosimilar products be truthful and not misleading. The following are key considerations for developing promotional materials for biological reference and biosimilar products:

Nomenclature: Clearly and correctly identify reference and biosimilar products according to the FDA-approved labeling.

The draft guidance recommends that promotional materials correctly and specifically identify the product or products to which the information applies, noting that biological products might be identified by a proprietary name (trademark or brand name), proper name (nonproprietary name designated by FDA in the license), or core name (component shared by the reference and biosimilar products). For example, if a biosimilar's FDA-approved labeling uses the core name of the reference product when describing risks for both of the products, then promotional material for the biosimilar should also use the core name for presentation about its risks. The correct use of nomenclature can help prevent presentations that are misleading because they attribute data or information to the wrong product.

Clinical Studies Supporting Licensure of the Reference Product: Refer to the biosimilar's FDA-approved labeling for clinical studies about the reference product.

When developing promotional materials for a biosimilar product that include information from the studies conducted to support licensure of the reference product that are reflected in both the reference product's FDA-approved labeling and the biosimilar's FDA-approved labeling, companies should refer to the biosimilar product's FDA-approved labeling.

Biosimilarity Studies: Present biosimilarity studies consistent with the CFL Guidance.

Since information supporting a demonstration of biosimilarity is not generally included in FDA-approved labeling, biosimilar companies wishing to include biosimilarity data in their promotional materials should follow principles outlined in FDA's guidance, *Medical Product Communications That Are Consistent With the FDA-Required Labeling — Questions and Answers* ("CFL Guidance").[6] Under the CFL Guidance, presentations of biosimilarity data should be consistent with the biosimilar's FDA-approved labeling and be truthful and non-misleading. For biosimilarity data presentations determined to be CFL, companies should provide contextual information about the study design and methodology, and any material limitations of the data.[7]

Comparisons: Promotional materials should avoid misleading comparisons between reference and biosimilar products.

FDA acknowledges that, because the licensing process for biosimilar products under 351(k) of the Public Health Service (PHS) Act involves a determination that the biological product is "highly similar" to the reference product,[8] the agency is inherently skeptical of promotional materials that suggest clinically meaningful differences between reference and

biosimilar products. For example, promotional materials that suggest a reference product is more effective than its biosimilar, or a biosimilar is safer than its reference product, will likely be considered false or misleading. Further, even promotional materials that include factual information, such as the difference in the number of indications between a reference and biosimilar product, could be considered misleading if the materials give the impression that the biosimilar product is less safe or effective because it is licensed for fewer indications.

Although the agency may have determined that a biosimilar is highly similar to the reference product, promotional materials for biosimilars should avoid suggesting that the reference product and biosimilar are identical. Similarly, promotional materials for a reference product should not suggest that the licensed biosimilar is not as safe or effective as the reference product because it is not identical to it. Further, biosimilar products that have not been licensed as interchangeable with the reference product should not include information in promotional materials that may suggest the biosimilar is interchangeable.

CONCLUSION

FDA is requesting comments on the draft guidance, and is specifically interested in input on promotional considerations that may be unique to interchangeable biosimilars.[9] The comment period, which ends April 6, 2020, overlaps with an "FDA/FTC Workshop on a Competitive Marketplace for Biosimilars" scheduled for March 9, 2020, which is being held in furtherance of another joint goal of the FDA and FTC to conduct public outreach efforts.[10]

The joint activities of the FDA ad FTC signal heightened awareness and scrutiny of advertising and promotion of biological reference products and biosimilar products. Coupled with broader outreach and education to further consumer and healthcare professional understanding about biosimilar products, these activities may prompt complaints reported to the Bad Ad Program, competitor challenges, and potential inquiries and/or enforcement by FDA's Office of Prescription Drug Promotion and/or FTC for false or misleading promotion of biological reference and biosimilar products.

[1] FOOD & DRUG. ADMIN, GUIDANCE FOR INDUSTRY: PROMOTIONAL LABELING AND ADVERTISING CONSIDERATIONS FOR PRESCRIPTION BIOLOGICAL REFERENCE AND BIOSIMILAR PRODUCTS: QUESTIONS AND ANSWERS (Feb. 2020), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/promotional-labeling-and-advertising-considerations-prescription-biological-reference-and-biosimilar.
[2] *See* JOINT STATEMENT OF THE FOOD & DRUG ADMINISTRATION AND THE FEDERAL TRADE COMMISSION REGARDING A COLLABORATION TO ADVANCE COMPETITION IN THE BIOLOGIC MARKETPLACE (Feb. 3, 2020) [hereinafter "JOINT STATEMENT"], https://www.fda.gov/media/134864/download.
[3] *See generally*, FOOD & DRUG ADMIN., BIOSIMILARS ACTION PLAN: BALANCING INNOVATION AND COMPETITION (July 2018), https://www.fda.gov/media/114574/download.
[4] JOINT STATEMENT, *supra* note 2.
[5] PFIZER, INC., CITIZEN PETITION (Aug., 22 2018), https://www.regulations.gov/contentStreamer?documentId=FDA-2018-P-3281-0001&attachmentNumber=1&contentType=pdf, and FDA RESPONSE TO PFIZER, INC. CITIZEN PETITION (Feb. 4, 2020) [FDA-2018-P-3281], https://www.regulations.gov/contentStreamer?documentId=FDA-2018-P-3281-0013&attachmentNumber=1&contentType=pdf.
[6] *See* FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: MEDICAL PRODUCT COMMUNICATIONS THAT ARE CONSISTENT WITH THE FDA-REQUIRED LABELING – QUESTIONS AND ANSWERS (June 2018), https://www.fda.gov/media/133619/download.
[7] *Id*. at 13.
[8] 42 U.S.C. 262(k).
[9] Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products – Questions and Answers; Draft Guidance for Industry; Availability, 85 Fed. Reg. 6201 (Feb 4, 2020).
[10] Food and Drug Administration/Federal Trade Commission Workshop on a Competitive Marketplace for Biosimilars; Public Workshop; Request for Comments, 85 Fed Reg. 6203 (Feb. 4, 2020), https://www.federalregister.gov/documents/2020/02/04/2020-02101/food-and-drug-administrationfederal-trade-commission-workshop-on-a-competitive-marketplace-for.