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Client Alert

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FDA Updates Draft Guidance on Promotional Labeling and Advertising Considerations for Biological Reference Products and Biosimilars

On April 25, 2024, FDA published a revised draft guidance, Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products – Questions and Answers (hereafter, "Revised Draft Guidance").[1]

BACKGROUND

The Revised Draft Guidance is an update to an earlier version of the draft guidance issued in February 2020 (see our prior Client Alert summarizing the 2020 version).

As part of FDA's "Biosimilar Biological Product Reauthorization Performance Goals and Procedures" for fiscal years 2023-2027, which were released in conjunction with enactment of the Biosimilar User Fee Amendments of 2022 (BsUFA III),[2] FDA committed to publishing a draft guidance on promotional labeling and advertising considerations for interchangeable biosimilar products. FDA met its goal of publishing the draft guidance on or before September 30, 2024;[3] however, instead of issuing an entirely new draft guidance on this topic, FDA simply expanded the scope of the 2020 draft guidance to include interchangeable biosimilars.

KEY UPDATES

FDA's Federal Register notice announcing availability of the Revised Draft Guidance states that the revisions are intended to "address questions firms may have when developing FDA-regulated promotional communications for prescription reference products or prescription

biosimilar products, including interchangeable biosimilar products."[4] The Revised Draft Guidance includes "additional recommendations and an example for interchangeable biosimilar products."[5]

But for the inclusion of interchangeable biosimilar products, changes between the 2020 draft guidance and the Revised Draft Guidance are relatively minor. Where the 2020 draft guidance expressly excluded "considerations unique to promotional materials for interchangeable biosimilars,"[6] the purpose of the Revised Draft Guidance is to clearly include interchangeable biosimilar products. Overall, the questions and answers in the Revised Draft Guidance are essentially the same as the 2020 draft guidance, reproduced with minor editorial changes for clarity. The main substantive changes are two additions related to interchangeable products:

- Question 6 ("What else should firms consider when developing promotional communications for reference products or biosimilar products?") was updated to note that promotional communications should avoid representing or suggesting that a reference product or an interchangeable or non-interchangeable biosimilar product are less safe and effective than each other based on their licensure pathway.7
- Question 7 ("What are some examples of applying the considerations in this guidance to promotional communications?") includes a new example for interchangeable biosimilar products. In the new example, a fictional product, HILEZEO, is licensed as interchangeable with CLAREXANT. A different fictional product, OMPIRAM, is licensed as biosimilar to, but not interchangeable with, CLAREXANT. In this example, promotional communications for HILEZEO state that, unlike patients using OMPIRAM, patients using HILEZEO can be assured of HILEZEO's safety and effectiveness because HILEZEO is licensed as interchangeable with CLAREXANT. The Revised Draft Guidance explains that this presentation is misleading, because it suggests that HILEZEO is superior in safety and effectiveness to OMPIRAM.8

These two minor substantive updates to the draft guidance do not provide significant additional guidance about promotional communications for interchangeable biosimilar products; however, the general promotional considerations outlined in the other questions and answers in the Revised Draft Guidance now also apply to interchangeable biosimilars.

Lastly, the Revised Draft Guidance includes a new question and answer set (Question 9) to confirm that postmarketing reporting requirements for submitting promotional communications to FDA before or at the time of first use apply to reference and biosimilar products.

CONCLUSION

While the substantive updates to the Revised Draft Guidance related to interchangeable biosimilars are relatively minor, the publication of the guidance provides a new opportunity for stakeholders to provide comments on all aspects of the Revised Draft Guidance. Comments may be submitted to FDA (Docket FDA-2019-D-5473) by June 25, 2024.[9]

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[1] FDA, Draft Guidance for Industry: *Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products; Questions and Answers* (Apr. 2024), *available at* https://www.fda.gov/media/134862/download.
[2] FDA, Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027, *available at* https://www.fda.gov/media/152279/download.
[3] *Id.* at 29.
[4] FDA Notice of Availability; *Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products, and Interchangeable Biosimilar Products - Questions and Answers; Revised Draft Guidance for Industry; Availability*; 89 Fed. Reg. 31,757, 31,758 (Apr. 25, 2024).
[5] Revised Draft Guidance, at 2.
[6] FDA, Draft Guidance for Industry: *Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products - Questions and Answers,* at 2 (Feb. 2020).
[7] Revised Draft Guidance, at 8.
[8] *Id.* at 10.
[9] FDA, Docket No. FDA-2019-D-5473, https://www.regulations.gov/docket/FDA-2019-D-5473/document.