Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products Questions and Answers

Guidance for Industry

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
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Advertising

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Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products Questions and Answers Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance addresses questions firms[2] may have when developing FDA-regulated promotional labeling and advertisements (promotional materials)[3,4] for prescription reference products[5] licensed under 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a))

[1] This guidance has been prepared by the Office of Prescription Drug Promotion in consultation with the Office of Therapeutic Biologics and Biosimilars in the Center for Drug Evaluation and Research in cooperation with the Center for Biologics Evaluation and Research at the Food and Drug Administration.

[2] In this guidance, the term *firms* refers to manufacturers, packers, and distributors, including representatives of these entities, of biological products licensed under section 351(a) or (k) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a) or (k)).

[3] Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA's authority includes provisions addressing labeling for all drugs and advertisements for prescription drugs. See, e.g., section 502(a), (f), and (n) (21 U.S.C. 352(a), (f), and (n)); see also section 201(m) (21 U.S.C. 321(m) (defining *labeling*). If a biological product meets the definition of *drug* under section 201(g) of the FD&C Act (21 U.S.C. 321), it is subject to these provisions to the same extent as any other drug. See section 351(j) of the PHS Act (42 U.S.C. 262(j)).

[4] Promotional labeling is generally any labeling other than FDA-required labeling that is devised for promotion of the product. Promotional labeling may also have other functions in addition to promotion. Such promotional labeling can include printed, audio, or visual matter descriptive of a drug for which the labeling is disseminated by or on behalf of a drug's manufacturer, packer, or distributor (21 CFR 202.1(l)(2)). The FD&C Act does not define what constitutes an *advertisement* for a prescription drug, but FDA regulations provide several examples, including "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems" (21 CFR 202.1(l)(1)).

[5] The term *reference product* means the single biological product licensed under section 351(a) of the PHS Act against which a biological product is evaluated in an application submitted under section 351(k) of the PHS Act (section 351(i)(4) of the PHS Act (42 U.S.C. 262(i)(4))).

and prescription biosimilar products[6] licensed under section 351(k) of the PHS Act (42 U.S.C. 262(k)). The guidance discusses considerations for presenting data and information about reference or biosimilar products in these promotional materials in a truthful and non-misleading way. Although the guidance covers promotional issues involving both reference and biosimilar products, some questions and answers are focused on only biosimilar product promotional materials. This guidance does not discuss considerations unique to promotional materials for interchangeable biosimilars.[7]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Section 351(k) of the PHS Act, added by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), outlines an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product. A biosimilar is a biological product that is highly similar to the reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, or potency.[8,9]

To meet the standard for interchangeability, an applicant must (1) provide sufficient information to demonstrate biosimilarity to the reference product and (2) demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.[10]

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[6] In this guidance, the terms *biosimilar* and *biosimilar product* refer to a biological product that FDA has licensed as biosimilar to a reference product (see sections 351(i)(2) and (k)(2) of the PHS Act (42 U.S.C. 262(i)(2) and (k)(2))).

[7] In this guidance, the terms *interchangeable biosimilar* and *interchangeable product* refer to a biosimilar product that FDA has determined to be interchangeable with the reference product (see sections 351(i)(3) and (k)(4) of the PHS Act (42 U.S.C. 262(i)(3) and (k)(4))).

[8] See section 351(i)(2) of the PHS Act (42 U.S.C. 262(i)(2)).

[9] See 21 CFR 600.3(s). The standard for licensure of a biological product as potent under section 351(a) of the PHS Act has long been interpreted to include effectiveness.

[10] See section 351(k)(4) of the PHS Act (42 U.S.C. 262(k)(4)).

Once FDA licenses a biosimilar or interchangeable product, providers and patients can be assured of the safety and effectiveness of a biosimilar or an interchangeable product, just as they would be for the reference product.

As the number of licensed biosimilar products increases, FDA expects an increase in promotion involving reference and biosimilar products. FDA is providing this guidance to address questions firms may have when developing FDA-regulated promotional materials for reference products or biosimilar products. The guidance discusses considerations for presenting data and information about reference or biosimilar products in these promotional materials to help ensure that they are accurate, truthful, and non-misleading as required under the Federal Food, Drug, and Cosmetic (FD&C) Act and FDA's implementing regulations.[11]

III. QUESTIONS AND ANSWERS

Q1. What are the general requirements for the content of FDA-regulated promotional materials for reference products and biosimilar products?

Prescription drugs, including those that are reference products or biosimilar products, are subject to the FD&C Act and FDA's implementing regulations, including misbranding provisions that address advertisements and promotional labeling for prescription drugs issued by or on behalf of manufacturers, packers, or distributors.

Under the FD&C Act and FDA's implementing regulations, prescription drug promotional labeling and advertising must be truthful and non-misleading, convey information about a drug's efficacy and its risks in a balanced manner, and reveal material facts about the drug.[12] Whether a promotional presentation is truthful and non-misleading involves a fact-specific determination that takes into account such factors as how the information is presented, the type and quality of the data relied on to support the presentation, and contextual and disclosure considerations. FDA regulations also require that firms promptly revise promotional labeling and advertising for their biological products upon certain labeling changes, including labeling changes to risk information.[13]

Q2. How should firms identify reference products and biosimilar products in promotional materials?

Depending on the context, biological products, including reference and biosimilar products, may be identified by their proprietary name, nonproprietary or proper name, or core name. As used in

[11] See sections 201(n) and 502(a) and (n) of the FD&C Act (21 U.S.C. 321(n), 352(a) and (n)); 21 CFR 1.21(a) and 202.1(e)(5).

[12] Ibid.

[13] 21 CFR 601.12(a)(4).

this guidance, a biological product's proprietary name means the trademark or brand name.[14] A biological product's proper name is the nonproprietary name designated by FDA in the license for a biological product licensed under the PHS Act.[15,16] A biological product's 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.[17]

Firms should carefully evaluate the information presented in promotional materials for reference products or biosimilar products to ensure that in each instance where the promotional materials address a product or products, the materials correctly and specifically identify the product or products to which the information applies (e.g., the reference product, the biosimilar product, or both the reference product and the biosimilar).[18] For instance, 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,[19] it would also be appropriate for similar presentations about this risk in promotional materials for the biosimilar to use this nomenclature. Firms should also ensure that if promotional materials describe studies in which non-U.S.-licensed comparator biological products were used (or if promotional materials otherwise mention such products), the promotional materials accurately identify the non-U.S.-licensed comparator biological products.

Clearly and correctly identifying the relevant biological product or products in promotional materials can help prevent presentations that are inaccurate because they attribute data or information to the wrong product. It can also help the audience identify which product or products are the subject of a particular promotional presentation.

[14] See the guidance for industry *Nonproprietary Naming of Biological Products* (January 2017). We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[15] See section 351(a)(1)(B)(i) of the PHS Act (42 U.S.C. 262(a)(1)(B)(i)) and 21 CFR 600.3(k)).

[16] See the guidance for industry *Nonproprietary Naming of Biological Products.*

[17] Ibid.

[18] Firms should also consider the requirements related to the placement, size, prominence, and frequency of the proprietary name and established name in prescription drug labeling and advertisements (see 21 CFR 201.10(g); 202.1(b) through (d)). For biological products, these requirements pertain to the placement, size, prominence, and frequency of the proprietary name and proper name of the product.

[19] See the guidance for industry *Labeling for Biosimilar Products* (July 2018). The guidance recommends that in labeling sections where the risk applies to both the biosimilar product and the reference product, it would be appropriate to use the core name of the reference product followed by the word "products" to convey, for instance, that a risk or other information necessary for the safe use of the product applies to both the biosimilar product and the reference product. The guidance also explains, among other things, that the biosimilar product's proprietary name (or if a proprietary name is not available, the biosimilar product's proper name) should be used when providing directive statements and recommendations for preventing, monitoring, managing, or mitigating risks.

Q3. When developing promotional materials for biosimilars, what should firms consider if presenting information from the studies conducted to support licensure of the reference product when the information is included in the FDA-approved labeling of both the reference and the biosimilar products?

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, firms should refer to the biosimilar product's FDA-approved labeling. FDA has recommended that a biosimilar product's FDA-approved labeling incorporate relevant data and information from the reference product's FDA-approved labeling, including clinical data that supported FDA's finding of safety and effectiveness of the reference product.[20]

For instance, 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.[21] In general, a biosimilar product's FDA-approved labeling contains data and information from the CLINICAL STUDIES section of the reference product's FDA-approved labeling for the conditions of use for which the biosimilar product is licensed and also generally includes data from the reference product's FDA-approved labeling regarding clinical pharmacology studies, immunogenicity, and toxicity, among other information.

Q4. When developing promotional materials for biosimilars, what should firms consider if presenting data or information from studies conducted to support a demonstration of biosimilarity when the data or information is not included in the FDA-approved labeling for their biosimilar product?

If biosimilar promotional materials present data and information from studies that were conducted to support a demonstration of biosimilarity between the biosimilar product and the reference product but are not included in the biosimilar product's FDA-approved labeling, those presentations should be consistent with the biosimilar's FDA-approved labeling and be truthful and non-misleading, as described in the guidance for industry *Medical Product Communications That Are Consistent With the FDA-Required Labeling — Questions and Answers* (June 2018) (CFL guidance).

FDA has recommended that the FDA-approved labeling for a biosimilar product generally not include data and information from studies conducted to support a demonstration of biosimilarity

[20] See the guidance for industry *Labeling for Biosimilar Products.*

[21] In certain circumstances it may have been necessary to include information in the biosimilar product labeling relating to an indication(s) for which the biosimilar product is not licensed 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). See the guidance for industry *Labeling for Biosimilar Products.*

between the reference product and the biosimilar product.[22] However, firms developing promotional materials for their biosimilar products have expressed interest in communicating this information to health care providers or other interested parties. FDA encourages these firms to apply the principles outlined in the CFL guidance if the promotional materials for their biosimilar products include data or information from studies that supported the demonstration of biosimilarity between the biosimilar and the reference product, which generally will not be included in the biosimilar product's FDA-approved labeling.

Q5. What should firms consider when comparing reference products and biosimilar products in their promotional materials?

FDA's licensure of a biosimilar product means that the Agency has determined that the biosimilar is highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences in terms of safety purity, or potency. Although assessment of each promotional presentation involves a fact-specific determination, representations or suggestions that create an impression that there are clinically meaningful differences between the reference product and its biosimilar, such as promotional presentations representing or suggesting that a reference product is safer or more effective than its biosimilar product, or that a biosimilar is safer or more effective than its reference product are likely to be false or misleading.[23] Similarly, representations or suggestions that create an impression that a biosimilar is not highly similar to its reference product are likely to be false or misleading.

Accordingly, FDA recommends that firms carefully evaluate presentations that compare a reference product and a biosimilar product and 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.

For example,[24] a firm generates promotional materials for a biosimilar product and the materials present data and information on response rates in patients treated with the reference product alone, response rates in patients initially started on the biosimilar product, and response rates in patients transitioned from the reference product to the biosimilar product from a study supporting a demonstration of biosimilarity. The presentation includes a header that the biosimilar is just as effective as the reference product.

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[22] See footnote 20.

[23] False or misleading presentations about the safety or effectiveness of a prescription drug in its labeling or advertisements misbrand the product and thus cause its distribution in interstate commerce, among other actions, to be prohibited. See sections 201(n), 301(a), and 502(a) and (n) of the FD&C Act (21 U.S.C 321(n), 331(a), 352(a) and (n)); 21 CFR 1.21(a) and 202.1(e)(5).

[24] See the response for Q7 for additional explanation of the use of examples in this guidance.

This presentation would not create a misleading impression that there is a clinically meaningful difference between the reference product and the biosimilar so long as appropriate context is provided in the presentation.[25, 26] By contrast, the same data and information presented with a header that claims greater efficacy for the biosimilar product would be misleading.

Similarly, representations or suggestions 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 would be misleading. Representations or suggestions that the reference product is less safe or less effective than its biosimilar based on this study also would be misleading.

In some cases, individual statements of accurate information about a reference product or about a biosimilar product could contribute to a misleading presentation when provided in a comparative context. For example, presentations in promotional materials for a reference product comparing 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 would be misleading.

Where a biosimilar has not been directly studied in a particular indication (i.e., the biosimilar's licensure for the indication is based in part on extrapolation), representations or suggestions in promotional materials for the reference product that the biosimilar is less safe or less effective than the reference product in that indication because licensure for that indication was based in part on extrapolation also would be misleading.

Q6. What else should firms consider when developing promotional materials for reference products or biosimilar products?

Promotional presentations about a product's licensure as biosimilar to a reference product should accurately describe the biosimilar product. For instance, promotional materials for a biosimilar product that FDA has not licensed as interchangeable with the reference product should avoid creating an impression that the biosimilar has been licensed as interchangeable with the reference product, because this would not be accurate. Also, promotional materials for a reference product should avoid representing or suggesting that a biosimilar product is less safe or effective than its reference product because it has not been licensed as interchangeable with the reference product.

FDA also reminds firms that a biosimilar product is not required to be identical to the reference product in order to be licensed; rather, licensure means the biosimilar product has been found to

[25] For a discussion of contextual considerations, refer to the CFL guidance.

[26] See the guidance for industry *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product* (April 2015) (explains that "[c]linically meaningful differences could include a difference in the expected range of safety, purity, or potency of the proposed product and the reference product. By contrast, slight differences in rates of occurrence of certain adverse reactions between the two products ordinarily would not be considered clinically meaningful differences").

be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety, purity, and potency. Accordingly, promotional materials for a biosimilar product that represent or suggest that a finding of biosimilarity means that FDA determined that the reference product and biosimilar product are identical to one another generally would not be accurate. Additionally, FDA recommends that promotional materials for reference products avoid presentations that represent or suggest that the licensed biosimilar is not as safe and as effective as the reference product because it is not or may not be identical to the reference product.

Q7. What are some examples of applying the considerations in this guidance to promotional presentations?

The following examples are intended to illustrate some of the general considerations outlined in this guidance. The examples in this guidance contain hypothetical scenarios for illustrative purposes only and focus on the topics addressed by this guidance; they do not describe every aspect of the promotional material that would be necessary to satisfy all applicable requirements. As noted in Q1, whether a promotional presentation is truthful and non-misleading involves a fact-specific determination that takes into account such factors as how the information is presented, the type and quality of the data relied on to support the presentation, and contextual and disclosure considerations.

The examples that follow use a fictional reference product JUNEXANT (replicamab-hjxf) and a fictional biosimilar to JUNEXANT, a product named NEXSYMEO (replicamab-cznm).

Examples 1 and 2 illustrate scenarios where FDA would *not* expect to object to the presentations described.

> ***Example 1:*** A firm is developing promotional materials for its biosimilar, NEXSYMEO. In the materials, the firm includes the route of administration, dosage form, and strength described in NEXSYMEO's labeling and a claim that NEXSYMEO has the same route of administration, dosage form, and strength as JUNEXANT in the conditions of use for which both products are licensed. The claim is supported by NEXSYMEO's licensure as biosimilar to JUNEXANT given that NEXSYMEO's licensure is based, in part, on information showing that the route of administration, dosage form, and strength of NEXSYMEO are the same as those of JUNEXANT.[27]
>
> Additionally, the materials include a claim that NEXSYMEO can be considered for patients who are new to replicamab product therapy for the treatment of a licensed indication and for patients currently being treated with JUNEXANT for the same indication. This claim is supported by data and information submitted as part of NEXSYMEO's application for licensure as biosimilar to JUNEXANT, including data from a comparative clinical study that included patients who underwent a single transition from JUNEXANT to NEXSYMEO and patients who were new to replicamab

[27] See section 351(k)(2) of the PHS Act (42 U.S.C. 262(k)(2)).

product therapy, which supported a demonstration of no clinically meaningful differences between NEXSYMEO and JUNEXANT in terms of safety, purity, and potency.

Example 2: As part of NEXSYMEO's application for licensure as biosimilar to JUNEXANT, FDA evaluated a comparative clinical study that included patients treated with a non-U.S.-licensed comparator product to support a demonstration of no clinically meaningful differences between NEXSYMEO and JUNEXANT.

NEXSYMEO's firm wants to present data and information describing outcomes observed in this study in promotional materials for NEXSYMEO. Data from this study is not included in the FDA-approved labeling for NEXSYMEO.

The firm develops a presentation consistent with the CFL guidance, including the recommendations in the CFL guidance regarding appropriate scientific and statistical support for the outcome information presented. The firm clearly and prominently provides contextual information about the study design and methodology, the role the study played in the biosimilarity evaluation, relevant data from NEXSYMEO's FDA-approved labeling, and any material limitations of the data. The firm also accurately describes the comparator used in the study as non-U.S.-licensed.

Example 3 illustrates promotional materials that FDA would consider misleading.

Example 3: Promotional materials for JUNEXANT state that in a clinical study, patients on JUNEXANT experienced a numerically higher overall response rate than patients on NEXSYMEO. The basis for the statement is a comparative clinical study that supported a demonstration of no clinically meaningful differences in terms of safety, purity, and potency between JUNEXANT and NEXSYMEO.

Although this statement accurately conveys the reference product's higher numeric overall response rates observed in the study, the materials do not disclose that this difference in response rates was not statistically significant, and they do not describe the study design or include other appropriate context. By focusing on the numerical difference in response rates, which was not statistically significant, the presentation misleadingly implies that JUNEXANT is superior to NEXSYMEO. It also misleadingly implies that there is a clinically meaningful difference between the products when the data presented in the promotional materials do not support this conclusion.

Q8. How can firms request FDA review of draft promotional materials for reference products and biosimilar products before their dissemination?

Firms voluntarily seeking FDA feedback on promotional materials for reference products or biosimilar products before their dissemination should follow the current process for submitting draft promotional materials for comment.[28]

Furthermore, FDA reminds firms that they are subject to the postmarketing reporting requirements for submitting promotional materials to FDA (Form FDA 2253 submissions for prescription drugs and biologics).[29, 30] In addition to the considerations specifically outlined in this guidance, firms should ensure that their FDA-regulated promotional materials otherwise satisfy the applicable requirements of the FD&C Act and FDA's implementing regulations.[31] Firms should also ensure that they comply with the provisions obligating them to update the FDA-approved labeling for their products to ensure that the labeling is not false or misleading or for other reasons.[32]

[28] See 21 CFR 202.1(j)(4). See also the guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs* (June 2019) and the draft guidance for industry *Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics* (July 2014). When final, this guidance will represent FDA's current thinking on this topic.

[29] See 21 CFR 601.12(f)(4)), section 745A(a) of the FD&C Act (21 U.S.C. 379k-1).

[30] For additional guidance on electronic submission of these materials, see footnote 29.

[31] See, e.g., sections 502(a) and (n) of the FD&C Act (21 U.S.C. 352(a) and (n)); 21 CFR 1.21(a) and 202.1(e)(5).

[32] See, e.g., 21 CFR 201.56(a)(2) (referring to labeling updates in accordance with 21 CFR 601.12); sections 502(a), (f), and (j) (21 U.S.C. 352(a), (f), and (j)).