
Direct-to-Consumer Prescription
Drug Advertisements:
Presentation of the Major
Statement in a Clear,
Conspicuous, and Neutral Manner
in Advertisements in Television
and Radio Format Final Rule
Questions and Answers
Guidance for Industry

(Small Entity Compliance Guide)

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

December 2023
Advertising

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Small Entity Compliance Guide

This guidance represents 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 office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance is intended to help small entities understand and comply with the standards established in the final rule, “Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format” (CCN Final Rule) (88 FR 80958, November 21, 2023). Section 502(n) of the Federal Food, Drug and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Amendments Act of 2007 (FDAAA),² requires that human prescription drug³ advertisements presented directly to consumers (DTC) in television or radio format that state the name of the drug and its conditions of use (DTC TV/radio ads) present the major statement relating to side effects and contraindications (“major statement”) in a clear, conspicuous, and neutral manner. The CCN Final Rule modifies 21 CFR 202.1(e)(1) to reflect this requirement and establishes standards to help ensure the major statement in these advertisements is presented in the manner required.

¹ This guidance has been prepared by the Office of Prescription Drug Promotion 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 See section 901(d)(3) of FDAAA (Public Law 110-85).

³ The term *drugs* in this guidance refers to prescription human drug and biological products.

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The major statement provides information relating to the major side effects and contraindications of an advertised prescription drug. Note that this is a selected presentation of the *major* side effects and contraindications of the drug and not a listing of every risk.⁴ DTC TV/radio ads are required to include a major statement.⁵

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 guidance means that something is suggested or recommended, but not required.

II. QUESTIONS AND ANSWERS

Q1. Which advertisements are subject to the standards established in the CCN Final Rule?

The standards established by the CCN Final Rule apply to advertisements for human prescription drugs that:

- Are presented directly to consumers,
- Are in television or radio format, and
- State the name of the drug and its condition(s) of use.

Q2. What is the compliance date for the CCN Final Rule?

Firms⁶ have until November 20, 2024, to bring all DTC TV/radio ads subject to the CCN standards into compliance.

Q3. Do the standards established in the CCN Final Rule change the content of the major statement?

No. The content of the major statement (e.g., the major side effects and contraindications) is not changed by this final rule.

Q4. How can a firm know whether its major statement is presented in a clear, conspicuous, and neutral manner?

⁴ The regulations allow DTC TV/radio ads subject to the CCN Final Rule (among other ads) to present only the major side effects and contraindications of the advertised drug (rather than also including "a brief summary of all necessary information related to side effects and contraindications") if the ads tell viewers or listeners how to get the full FDA-approved prescribing information. See 21 CFR 202.1(e)(1)(i).

⁵ See 21 CFR 202.1(e)(1).

⁶ The term *firms* in this guidance refers to manufacturers, packers, and distributors of any human prescription drug that is distributed or offered for sale in any State who advertise that drug, and to all persons who they cause to issue any advertisement with respect to their human prescription drug(s), including both individuals and corporate entities.

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FDA established standards to help ensure that the presentation of the major statement is clear, conspicuous, and neutral. The standards are:

- **Standard 1 (21 CFR 202.1(e)(1)(ii)(A)):** The major statement is presented in consumer-friendly language and terminology that is readily understandable.
- **Standard 2 (21 CFR 202.1(e)(1)(ii)(B)):** The major statement's audio information, in terms of the volume, articulation, and pacing used, is at least as understandable as the audio information presented in the rest of the advertisement.
- **Standard 3 (21 CFR 202.1(e)(1)(ii)(C)):** In advertisements in television format, the major statement is presented concurrently using both audio and text (dual modality). To achieve dual modality:
 - Either the text displays the verbatim key terms or phrases from the corresponding audio, or the text displays the verbatim complete transcript of the corresponding audio; and
 - The text is displayed for a sufficient duration to allow it to be read easily. For purposes of the standard in the paragraph (e)(1)(ii)(C)(2), the duration is considered sufficient if the text display begins at the same time and ends at approximately the same time as the corresponding audio.
- **Standard 4 (21 CFR 202.1(e)(1)(ii)(D)):** In advertisements in television format, for the text portion of the major statement, the size and style of font, the contrast with the background, and the placement on the screen allow the information to be read easily.
- **Standard 5 (21 CFR 202.1(e)(1)(ii)(E)):** During the presentation of the major statement, the advertisement does not include audio or visual elements, alone or in combination, that are likely to interfere with comprehension of the major statement.

As noted in the text of standards three and four, those standards apply only to advertisements in television format.

Q5. How can firms comply with Standard 1?

Standard 1 requires that the major statement be presented in consumer-friendly language and terminology that is readily understandable (21 CFR 202.1(e)(1)(ii)(A)). This means that firms must use consumer-friendly language and terminology that is readily understandable, rather than medical or technical jargon or terms usually more familiar to health care providers. To comply with this standard, firms must also avoid language or terminology in the presentation of the major statement that is so vague as to be readily subject to different interpretations.

The CCN Final Rule does not require the use of language associated with a particular grade level of reading or similar criterion, as FDA recognizes that it may be necessary to include certain

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terms in the major statement (e.g., a reference to a disease like “tuberculosis”) that could result in a relatively high grade level rating. The standard requires that the risk information is understandable to the ordinary consumer while providing firms with flexibility in designing their DTC TV/radio ads.

Q6. How can firms comply with Standard 2?

Standard 2 requires that the audio presentation of the major statement be at least as understandable as the audio presentation of other information in the advertisement in terms of volume, articulation, and pacing (21 CFR 202.1(e)(1)(ii)(B)).

To comply with this standard, firms should consider the volume, articulation, and pacing of the audio presentation of the major statement in the advertisement to ensure that the audio presentation of the major statement is as understandable as or more understandable than the audio presentation of other information in the advertisement.

Q7. How can firms comply with Standard 3?

Standard 3 requires that for advertisements in television format, the major statement be presented concurrently using both audio and text (dual modality).

To achieve dual modality:

- Either the text displays the verbatim key terms or phrases from the corresponding audio, or the text displays a verbatim complete transcript of the corresponding audio; and
- The text is displayed for a sufficient duration to allow it to be read easily. For the purposes of the standard in the paragraph (e)(1)(ii)(C)(2), the duration is considered sufficient if the text display begins at the same time and ends at approximately the same time as the corresponding audio (21 CFR 202.1(e)(1)(ii)(C)).

Firms have flexibility in determining how they choose to comply with the first prong of this standard. They can either use text to display key words or phrases, using the same words used in the corresponding audio presentation of the major statement (not synonyms), or they can display a complete transcript of the corresponding audio, using the same words used in the corresponding audio.

For example, if the audio states, “The most common side effects of DRUGX are dry mouth, headache, and heartburn,” the firm could display the full transcript of that statement as shown. The firm could also display “• dry mouth • headache • heartburn.”

To comply with Standard 3, a firm also must ensure that the display of textual information in the major statement appears for a sufficient duration to allow it to be read easily. The regulation provides that this requirement is met if the ad begins displaying the major statement text at the same time that the corresponding major statement audio information begins and stops displaying the text at approximately the same time that the corresponding audio information ends. Note that

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the pacing of the audio presentation of the major statement must enable the ad to satisfy Standard 2 (21 CFR 202.1(e)(1)(ii)(B)). See Q6.

Q8. How can firms comply with Standard 4?

Standard 4 requires that for the text portion of the major statement in advertisements in television format, the size and style of font, the contrast with the background, and the placement on the screen allow the information to be read easily (21 CFR 202.1(e)(1)(ii)(D)). Note that Standard 4 applies to the presentation of the major statement and not to other textual information in the advertisement.

To comply with this standard, firms are required to ensure that the presentation of the text of the major statement is easily readable. Firms are not required to use particular font colors, sizes, placement, or backgrounds but instead are required to ensure that these aspects of text in combination result in an easily readable presentation of the major statement. More than one combination may allow for the textual information to be read easily. For example, increasing the amount of contrast between the font and the background may improve readability. And, even at a smaller size, some styles of font are more easily read compared to others.

Q9. How can firms comply with Standard 5?

Standard 5 requires that during the presentation of the major statement, the advertisement does not include audio or visual elements, alone or in combination, that are likely to interfere with comprehension of the major statement (21 CFR 202.1(e)(1)(ii)(E)). Standard 5 applies only to the portion of the advertisement during which the major statement is presented.

To comply with this requirement, firms must ensure that their DTC TV/radio ads do not include audio or visual elements (music, sounds, text, images, etc.) during the presentation of the major statement that, alone or in combination, are likely to interfere with comprehension of the major statement.

Not all audio or visual elements are likely to interfere with comprehension of the major statement. In fact, by requiring dual modality—the concurrent use of both text (a visual element) and audio to present the major statement in advertisements in TV format—the CCN Final Rule acknowledges that multiple elements can actually be used to reinforce risk information.

This standard does not categorically prohibit use of other creative elements during the major statement. It also does not prohibit narrower categories of elements (e.g., it does not bar all music, sound effects, drawings). The standard does not even categorically prohibit any subtypes of elements (e.g., it does not bar upbeat music or amusing drawings).

Firms should examine the facts and circumstances presented by a specific advertisement to ensure that the advertisement complies with this standard.

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Q10. Does FDA provide any resources to firms to help ensure that an advertisement complies with the CCN Final Rule?

Firms may voluntarily request comments from FDA on proposed DTC TV/radio ads before their dissemination.⁷ Reviewers in FDA’s Office of Prescription Drug Promotion (OPDP) within the Center for Drug Evaluation and Research (CDER) and reviewers in the Advertising and Promotional Labeling Branch (APLB) within the Center for Biologics Evaluation and Research (CBER) will evaluate the draft materials that firms submit for, among other things, compliance with the CCN Final Rule. Reviewers provide comments back to firms for their consideration.

⁷ See 21 CFR 202.1(j)(4) and the guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs* (April 2022). 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>. For questions about submissions to OPDP, contact the OPDP Project Manager at CDER-OPDP-RPM@fda.hhs.gov.