

FDA Guidance on Direct-to-Consumer Prescription Drug Advertisements

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In December 2023, the [Federal Drug Administration](#) issued guidance on the topic “Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format Final Rule”

This guidance is not binding on the public or the FDA. The guidance does represent the current view of the FDA. The guidance was created to help advertisers advertise drugs to consumers. [The FDA](#), under its authority based on the Food, Drug, and Cosmetic Act (FD&C Act), regulates drugs, food, medical devices, vaccines, blood, biologics, cosmetics, tobacco, and animal and veterinary products.

The FD&C Act, as amended in 2007 requires that direct-to-consumer (DTC) TV and radio ads identify the name of the drug and the conditions of use including the side effects and contraindications (“major statement”) in a clear, conspicuous, and neutral (CCN) manner. The guidance set forth in the agency’s [CNN Final Rule](#) creates standards to ensure the major statement in these DTC TV and radio ads is properly presented.

The CNN Final Rule generally applies to pharmaceutical companies that use TV and the radio to advertise their products. These companies should also review with legal counsel the various regulations that govern advertising through the Internet and through print and social media advertising.

Questions and answers about the Direct to Consumer TV and Radio drug ads

The FDA begins by stating that that list of major side effects and contraindications is not a list of every risk. The guidance documents do not create “legally enforceable responsibilities.” The guidance recommendations are recommendations. To understand what FDA requirements are enforceable, please speak with our experienced FDA compliance lawyers. We’ll explain what laws and regulations govern FDA compliance and what steps you can take to help show that you are in compliance. We’ll also explain that while the guidelines may not be directly enforceable, compliance with the rules is generally advisable.

Avoid common FDA mistakes marketing health products

Avoid these common FDA mistakes marketing health products: communicating with FDA without legal counsel, making disease claims, misunderstanding the rules.

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

The FDA DTC guidance recommendations apply to human prescription drug ads that:

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

What is the compliance date for the CCN Final Rule?

Advertisers should work to show that their DTC TV and radio ads are in compliance by no later than November 20, 2024.

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

No. The identification of major side effects and contraindications “is not changed by this final rule.”

How can pharmaceutical companies and other advertisers know whether their major statement is “presented in a clear, conspicuous, and neutral manner?”

FDA established the following five standards to help ensure that the major statement is being presented – clearly, conspicuously, and that the major statement is neutral. The five standards are:

- Standard 1 (21 CFR 202.1(e)(1)(ii)(A)). The major statement language should be consumer-friendly and consumers should be able to readily understand the terminology.
- Standard 2 (21 CFR 202.1(e)(1)(ii)(B)). The audio part of the major statement that discusses the major statement should be at least as understandable – in terms of the “volume, articulation, and pacing used” – as the audio information presented in the rest of the advertisement.
- Standard 3 (21 CFR 202.1(e)(1)(ii)(C)). In television advertisements, the major statement should be “presented concurrently using both audio and text (dual modality).” Dual modality should be obtained:
 - Either by displaying the key terms or phrases of the text verbatim with the corresponding audio or the text should be displayed verbatim with the complete transcript of the corresponding audio
 - The text should be shown for a sufficient duration so the text can be read easily. The CNN Final Rule further details the amount of time that is considered “sufficient.”
- Standard 4 (21 CFR 202.1(e)(1)(ii)(D)). TV ads should include a text portion of the major statement. The size and style of the font, the contrast with the background, and the placement on the screen should all allow for the text/information to be read easily.
- Standard 5 (21 CFR 202.1(e)(1)(ii)(E)). While the major statement is being presented, the advertisement should “not include audio or visual elements, alone or in combination, that are likely to interfere with comprehension of the major statement.”

Standard 1 compliance requirements – the major statement should be consumer-friendly and understandable

The emphasis on consumer-friendly language and readily understandable terminology means that advertisers should avoid using medical or technical jargon or terms that healthcare providers are more likely to use and understand. The language and terms should not be ambiguous or vague – open to different interpretations.

The CCN Final Rule does not use a reading scale or grade level scale such as – understandable at a 10th-grade level. FDA does understand that some medical language (such as referring to a disease like “tuberculosis”) will be necessary. Standard 1 does require that ordinary consumers should be able to understand the risks – but does give advertisers some flexibility in designing their DTC TV/radio ads.

When Will FDA Likely Regulate Your Product as an OTC Drug and Not a Cosmetic?

In today's video, we talk about when your product is likely to cross the line and be regulated by the federal Food & Drug Administration ("FDA") as a cosmetic and not a prescription or Over the [...]

Standard 2 compliance requirements – the major statement should be comparable to the rest of the advertisement

The CNN Final Rule requires that advertisers review the volume, the articulation, and the pacing of the audio. The volume shouldn't be softer than the rest of the ad. The pace shouldn't be faster than the rest of the ad – consumers need to be able to absorb the information. The articulation should enable consumers to understand the words in the major statement.

Standard 3 compliance requirements – the dual modality (audio and text) requirement for television advertisements

Advertisers have some discretion about how they present the text which explains the key parts of the major statement. Advertisers can either use the "same words used in the corresponding audio presentation of the major statement (not synonyms), or advertisers can display a complete transcript of the corresponding audio, using the same words used in the corresponding audio."

For example, if the audio part of the TV ad states, "The most common side effects of DRUGX are dry mouth, headache, and heartburn," the firm could display on the screen either of the following:

- Key phrases and terms – "• dry mouth • headache • heartburn."
- The full transcript – "The most common side effects of DRUGX are dry mouth, headache, and heartburn"

Standard 3 also requires that "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." In other words, the visual presentation and the audio sound must be in sync.

Standard 4 compliance requirements – TV ad text format, size, font style, contrast, and background requirements of the major statement

Standard 4 applies only to the major statement presentation. The presentation conditions should ensure that consumers should be able to easily read the advertisement. Bigger fonts are more legible than smaller fonts. Some fonts are easier to read than other fonts. Contrasts between the text and the background are also easier to read. The placement of the text should be where the consumer will focus their attention. The key focus is the overall combination of conditions. For example, smaller font sizes may be just as readable as bigger font sizes if a more legible type of font is used.

Standard 5 compliance requirements

This standard also only applies to the major statement portion – not the rest of the drug advertisement. Generally, the major statement presentation should not include sounds, music, text, or images that "alone or in combination, are likely to interfere with comprehension of the major statement."

The CNN Final Rule does recognize that "multiple elements can actually be used to reinforce risk information." The Rule doesn't specifically prohibit drawings, music, or sound effects. These elements may even help. The bottom line is that the consumer must be able to fully understand the risks and contraindications of the drug being advertised.

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

Advertisers can seek comments from the FDA about their ads – before the ad airs. The ads will be reviewed by people 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).”

Consumers have the right to know what side effects and contraindications of the drugs they take may be dangerous so consumers can make informed decisions. FDA in November 2023 provided a guide (a Final Rule) for advertisers about whether their TV and radio ads that promote drugs directly to consumers properly inform consumers about the drug’s side effects and contraindications. The clear, conspicuous, and neutral (CNN) Final Rule provided by the FDA includes 5 standards that pharmaceutical companies and advertisers should meet.

Informed Consent and Risk Waivers

The doctrine of informed consent is based on the principle that adults of sound mind should have the right to decide what can be done to their bodies.

Pharmaceutical companies and advertisers should contact Cohen Healthcare Law Group, PC to discuss their FDA compliance requirements. Our experienced healthcare attorneys advise medical companies about healthcare compliance laws and regulations.

Contact our healthcare law and FDA attorneys for legal advice relevant to your healthcare venture.