

“Clear, Conspicuous, and Neutral” (“CCN”)

Clarifying New Regulations



CCN RULE WENT INTO EFFECT:

MAY 20, 2024

COMPLIANCE DEADLINE:

NOVEMBER 20, 2024

What Does FDA Regulate?

The FDA regulates manufacturer-sponsored promotion of Rx drugs, including:

- TV and radio commercials,
- Sales aids, journal ads, and patient brochures, and
- Drug websites, social media posts, webinars, speeches, emails and text messages.

DTC Rx TV & Radio Commercials Must Include a “Major Statement”

Prescription drug TV and radio commercials aimed at consumers (DTC ads) must include a “major statement” about the drug’s side effects and contraindications. This major statement **does not** have to list every risk. FDA’s Final Rule requires that this major statement be presented in a clear, conspicuous and neutral (CCN) manner.

What Does The CCN Rule Apply To?

The CCN Rule applies to full product claim ads (ads that include both the drug name and its uses):

- For human Rx drug ads
- Directed to consumers (“DTC”)
- In television or radio format*

*Though the CCN rule technically only applies to “broadcast” and “telephone communication systems” ads, we expect FDA to apply the rule to commercials on streaming platforms, social media, and smart/connected TVs.

What Does The CCN Rule Not Apply To?

The CCN Rule does not apply to:

- Commercials that don’t include the drug name + uses, such as:
 - reminder ads,
 - help-seeking and disease awareness ads, and
 - institutional/company-specific ads
- Print ads*

*FDA doesn’t address static ads presented digitally on screens and wallboards. These types of digital ads don’t have any audio component and the visual presentation doesn’t animate, though the Important Safety Information (ISI) may be scrolling on the screen. We think that if a digital ad is static and silent, and the only part of the ad that moves is scrolling ISI, the ad is more like a traditional print ad or social media text-based ad than a TV or radio commercial. Where a digital ad doesn’t have the audio or audio and visual distractions to a consumer’s comprehension of a drug’s risks that the CCN Rule is addressing, we believe it can be argued that the CCN Rule doesn’t apply. Static and silent ads on digital screens and wallboards would still need to comply with other FDA requirements and would have to continue to include the ISI if the ad type is a product claim ad. Manufacturer sponsors are expecting that all their video and audio Rx human drug DTC ads comply with the CCN Rule.

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FDA Has 5 Standards For The Presentation Of A CCN Major Statement In Radio and TV Commercials.

- 1 Easy to Understand Language:** The major statement should use words familiar to consumers, not medical jargon.
 - 2 Clear Audio:** The spoken presentation of the major statement must be as clear as the rest of the ad in terms of volume, speaking speed, and pronunciation.
 - 3 Dual Modality in TV Ads:** Both audio and text (captions) must be used at the same time to present the major statement.
 - 4 Easy-to-Read Text:** The text size, font style, color contrast with the background, and placement on the screen must allow viewers to read the major statement information easily.
 - 5 No Distractions:** The ad should not have any elements that could make it difficult to understand the major statement.
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When Do Ads Have to Comply with the CCN Rule?

The CCN Rule went into effect on **May 20, 2024**. However, drug companies have until **November 20, 2024** to bring their ads into compliance.

Where Can I Get More Information From FDA?

- The CCN rule, [21 C.F.R. § 202.1\(e\)\(1\)](#).
- [FDA Q&A Compliance Guidance for Industry \(Dec. 2023\) explains](#) the CCN Rule's 5 standards in more detail.
- [FDA April 10, 2024 presentation](#) repeats the Q&A and gives additional explanations of the CCN Rule's 5 standards.
- [FDA FAQ](#).

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4 Types of Drug Ads

There are different types of drug ads, with varying levels of detail about the medication:

<p>Product Claim Ads</p> <p>Compliant FDA example here</p>	<p>A full product claim ad identifies the drug's brand and generic names and includes accurate information about the drug's use. A permissible product claim ad should accurately state an FDA-approved use for the drug and that it is Rx. The ad must include a "fair balance" of risks and benefits. The ad includes a required statement for how to report side effects and provides sources of further information. Print ads include a "brief summary" of risks. A full product ad also identifies the company sponsoring the ad and provides ways to obtain more information.</p> <p>TV/radio ads must also include a “major statement” of risks presented in a CCN manner. TV/radio ads must make adequate provision for the PI or provide brief summary of risks.</p>
<p>Help-Seeking Ads</p> <p>Compliant FDA example here</p>	<p>A help-seeking ad describes a disease or condition but cannot identify the Rx drug by name. The ad recommends readers seek healthcare provider advice, identifies the company sponsoring the ad, and provides ways to obtain more information.</p> <p>Help-seeking ads do not require a major statement, brief summary, fair balance, or the CCN disclosure.</p>
<p>Reminder Ads</p> <p>Compliant FDA example here</p>	<p>A reminder ad must identify the drug's brand name (if it has one) and its generic name. No other statements or claims about the Rx drug are permitted in a reminder ad, though an “Ask your doctor” statement is permitted.</p> <p>A reminder ad does not require a major statement, brief summary, fair balance, or CCN disclosure. Reminder ads are not permitted for boxed warning drugs.</p>
<p>Institutional Ads</p> <p>Compliant FDA example here</p>	<p>An institutional ad identifies the company and may describe the company's research/therapeutic focus.</p>