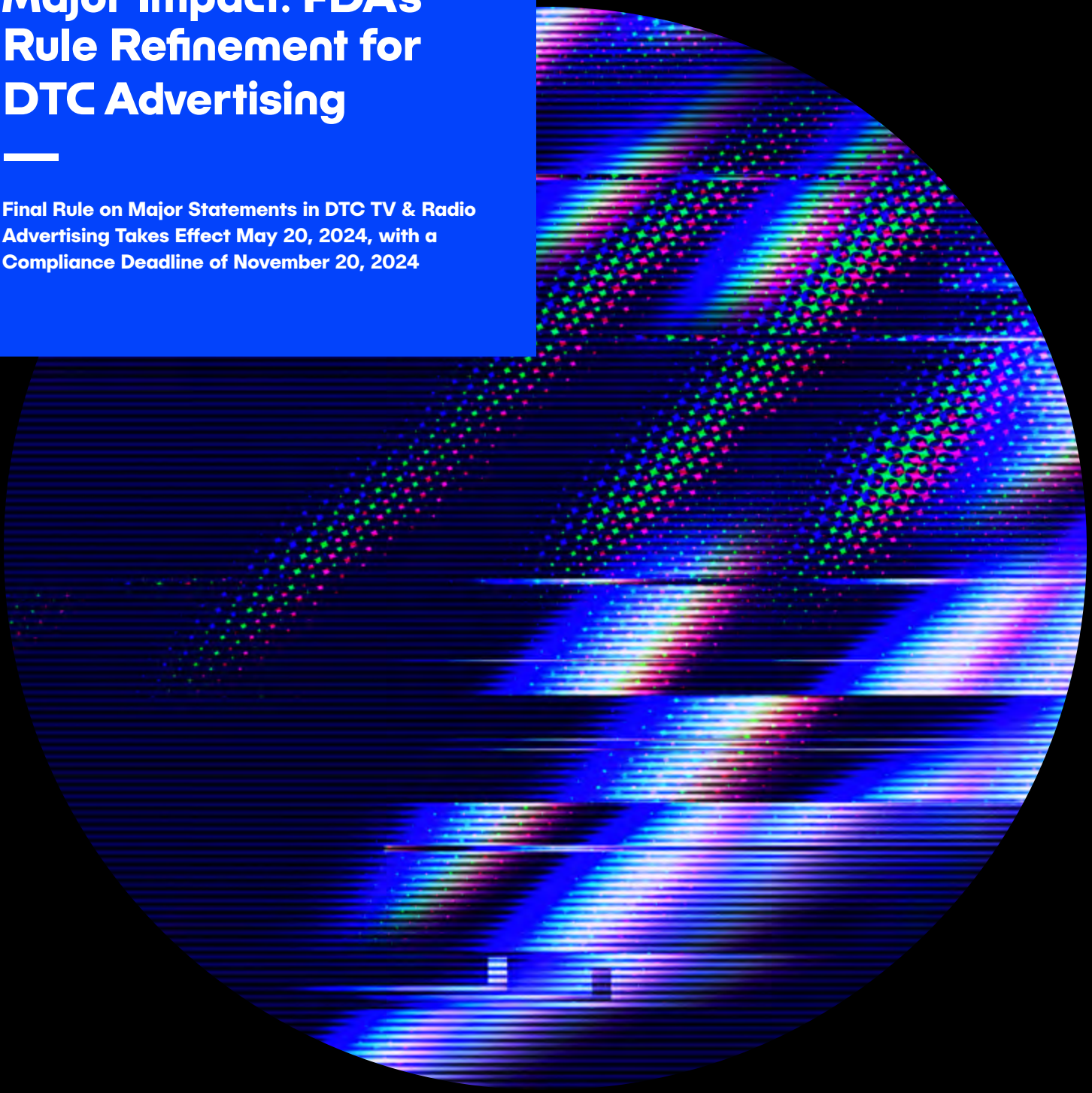
A Klick Health POV
Science + Regulatory

Major Statement, Major Impact: FDA's Rule Refinement for DTC Advertising

Final Rule on Major Statements in DTC TV & Radio Advertising Takes Effect May 20, 2024, with a Compliance Deadline of November 20, 2024



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FDA UNVEILS LONG-AWAITED FINAL RULE ON MAJOR STATEMENT PRESENTATION

Refined through extensive research and public feedback, the final rule underscores the major statement's role in presenting risk information clearly—balancing conciseness with comprehensiveness.

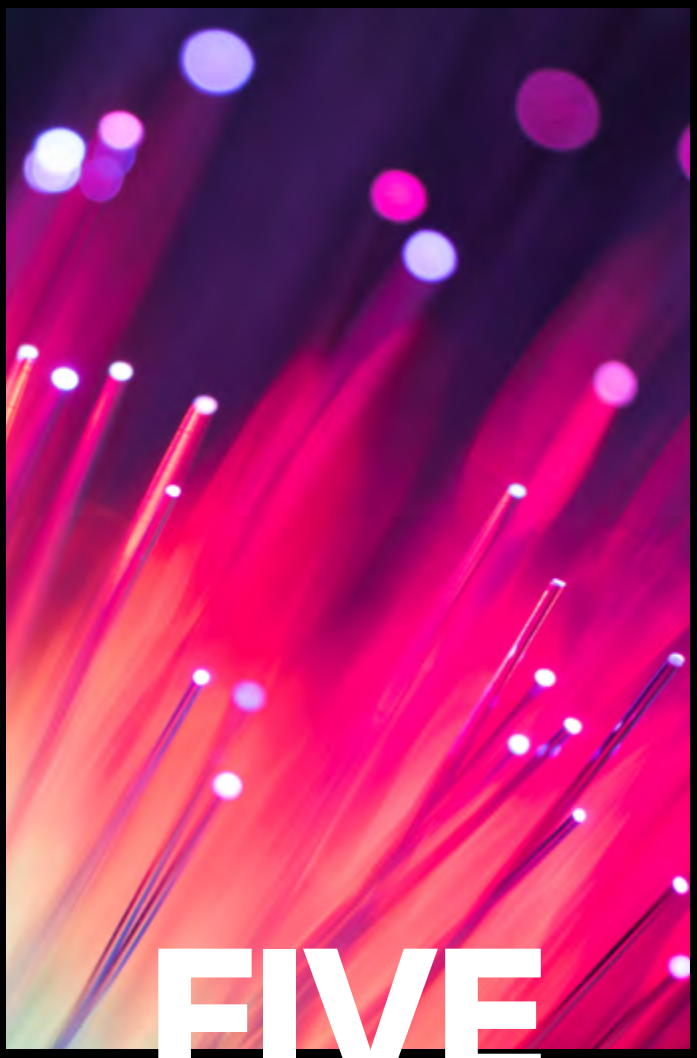
This POV provides background context, details on the contents of the final guidance, and Klick's recommendations for DTC TV and radio ads at any stage of the project lifecycle.

On November 21, 2023, the Food and Drug Administration (FDA) issued its final guidance for direct-to-consumer (DTC) human prescription drug advertisements for television and radio.

This update finalizes the proposed guidance from March 29, 2010, establishing **five standards** that ensure that the major statement relating to major side effects and contraindications in DTC TV and radio ads is presented in a **clear, conspicuous, and neutral** (CCN) manner.

This final rule does not change the required content of the major statement. Still, it will **likely require updates to the presentation of the major statement** in DTC TV ads that are currently live or in production to adhere to the new standard of "dual modality."

This rule will come into effect on May 20, 2024. Affected firms are encouraged to comply as soon as possible after this date; however, given the impact on existing ads, ads in production, and distribution agreements, the FDA has issued a **compliance date of November 20, 2024.**



FIVE STANDARDS FOR CCN PRESENTATION

The FDA's final rule presents five standards to ensure the major statement in DTC TV and radio ads is presented in a CCN manner.

// Use of terminology and language that is **easily understood**

// No specific grade level

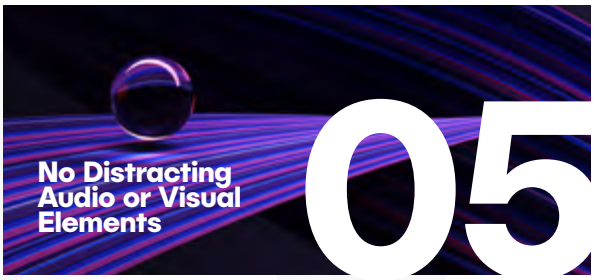
// Avoids vague terms

// Similar **volume, articulation,** and **pacing** as the rest of the ad

// Uses both audio and text: **dual modality**

// Key terms and phrases verbatim from audio **or** complete transcript of audio

// **Easy readability** against a contrasting background



// Avoids the use of **distracting audio or visual elements** during major statements such as music, sound effects, statements, text, and images

**Applies to DTC TV ads only*

01

CONSUMER-FRIENDLY LANGUAGE

The terminology and language of the major statement should be easily understood by consumers to avoid confusion and ensure transparency.

//

Notably, the FDA has opted not to prescribe a specific grade level or criterion, thus providing manufacturers with flexibility in designing their ads.

//

The FDA has not mandated the use of quantitative descriptors and instead advises against using vague terms subject to different interpretations.

HOW DOES THIS RULING BUILD ON THE PREVIOUS 2010 PROPOSED RULE?

PROPOSED 2010 STANDARD

"Information is presented in language that is readily understandable by consumers."

MINOR CHANGES

The proposed 2010 standard refers more generally to "information," whereas the final 2023 standard specifies that this applies to major statements, highlighting the need for "consumer-friendly" language and terminology.

Both the proposed standard and the final standard emphasize the use of language that is readily understandable by consumers.

02

UNDERSTANDABLE AUDIO INFORMATION

Audio information presented during the major statement must be at least as understandable as the audio information in the rest of the ad regarding volume, articulation, and pace. This is especially relevant for older adults and individuals who rely on the audio portions of the ad.

While the length of some major statements may be impacted to adhere to the final standards, the FDA indicates that this rule does not require DTC TV and radio ads to be longer.

HOW DOES THIS RULING BUILD ON THE PREVIOUS 2010 PROPOSED RULE?

PROPOSED 2010 STANDARD

"Audio information is understandable in terms of the volume, articulation, and pacing used."

MINOR CHANGES

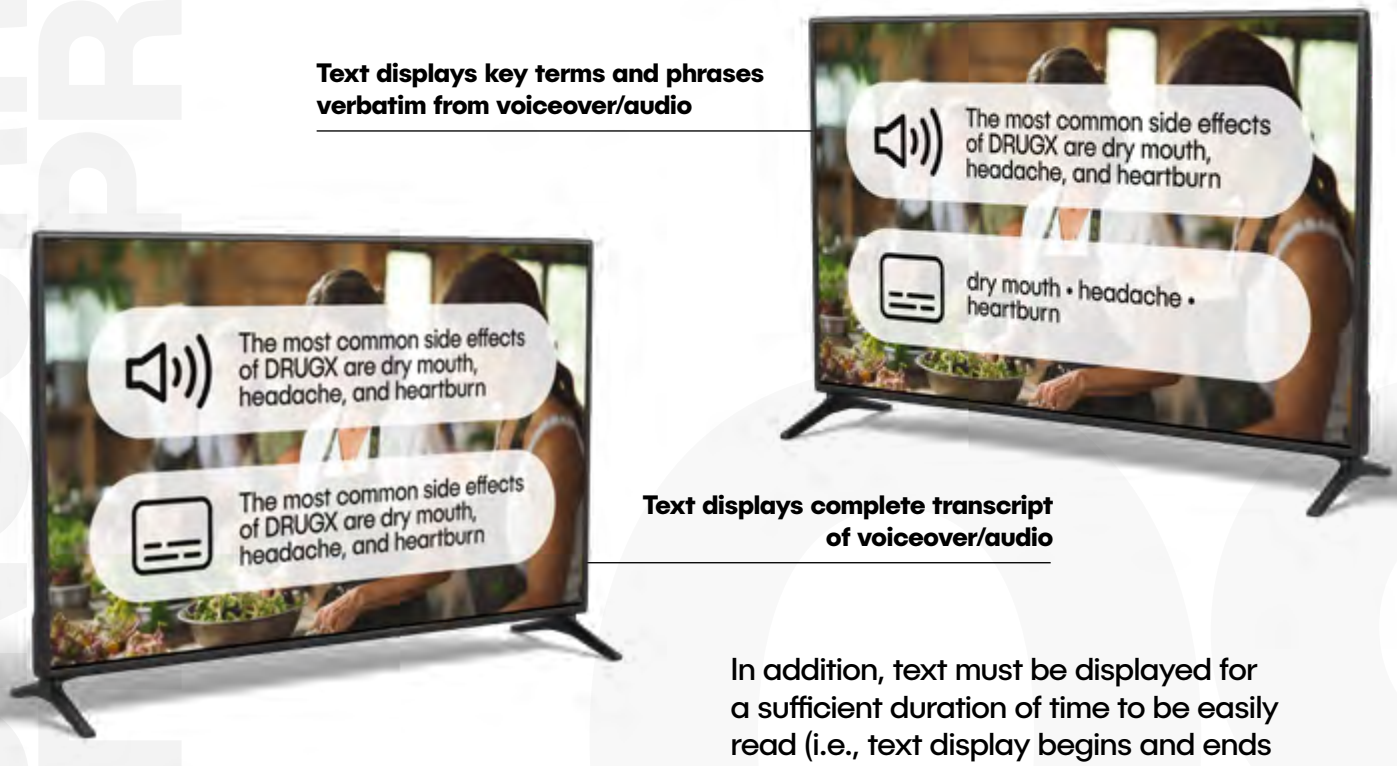
The final 2023 standard clarifies that the audio for the major statement should be at least as understandable as the audio information presented in the rest of the advertisement.

Both the proposed standard and the final standard highlight the importance of audio clarity in terms of volume, articulation, and pacing.

03

CONCURRENT AUDIO & TEXT PRESENTATION IN TV ADS

As per this standard, risk information must be presented concurrently using both audio (voiceover) and text (supers)—otherwise known as dual modality. To achieve dual modality, the supers can display a complete transcript of the voiceover or display key terms and phrases verbatim from the voiceover.



In addition, text must be displayed for a sufficient duration of time to be easily read (i.e., text display begins and ends at approximately the same time as corresponding audio).

HOW DOES THIS RULING BUILD ON THE PREVIOUS 2010 PROPOSED RULE?

PROPOSED 2010 STANDARD

"The major statement in television advertisements [must] be included in both the audio and visual parts of the presentation."

MAJOR CHANGES

The final 2023 standard builds on the proposed potential standard by introducing and prescribing the concept of dual modality, specifying that the text displayed during the major statement must begin and end at approximately the same time as the corresponding audio.

While this standard was only under consideration in the draft guidance, it has been codified in the final guidance.

04

READABLE TEXT FORMAT IN TV ADS

The FDA indicates requirements for the presentation of textual information in the major statement, emphasizing placement, duration, and readability. The standard applies specifically to the text portion of the major statement in TV ads, not textual information in the ad as a whole.

Supers should be in a size and style of font that allows for easy readability against a contrasting background, but there is flexibility within different presentational elements.

HOW DOES THIS RULING BUILD ON THE PREVIOUS 2010 PROPOSED RULE?

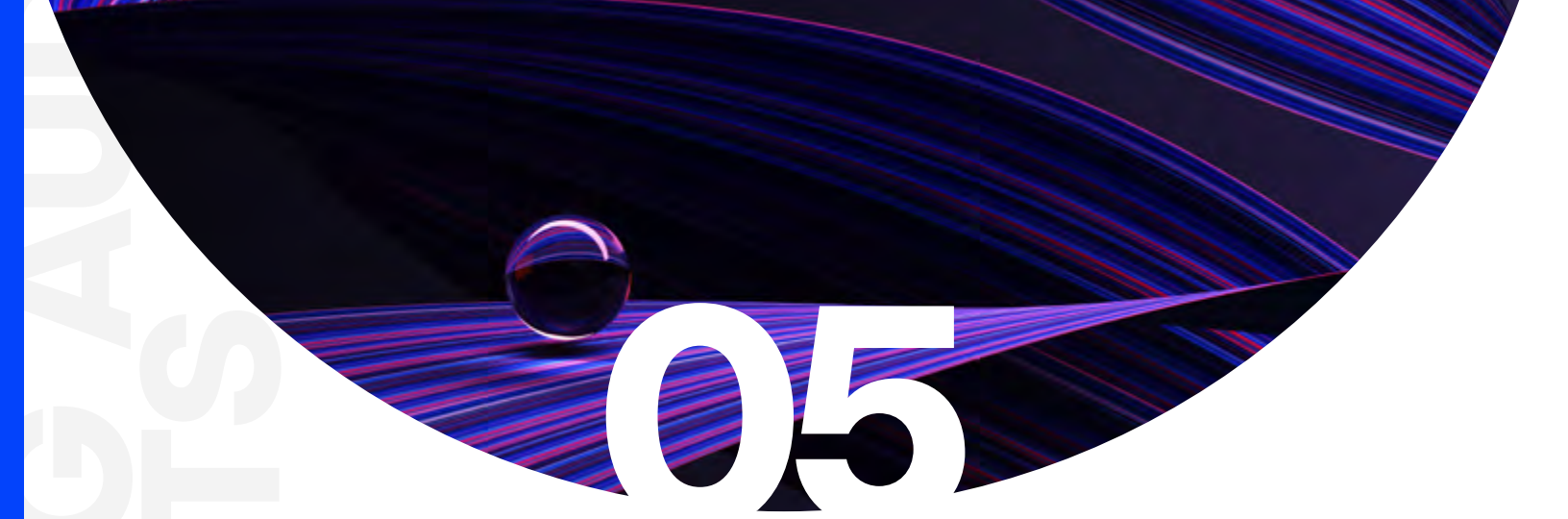
PROPOSED 2010 STANDARD

"Textual information is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily."

MINOR CHANGES

The final 2023 standard removes the provision for duration, as this is now covered by the dual modality standard.

Both the proposed standard and the final standard address the need for text to be easily readable through appropriate font size and style as well as contrast with the background.



05

NO DISTRACTING AUDIO OR VISUAL ELEMENTS

This standard precludes the use of audio or video elements during the presentation of the major statement that can interfere with viewer comprehension. These audio or visual elements include music, sound effects, statements, text, and images. However, this standard does not prohibit any subtypes of elements (i.e., upbeat music or amusing drawings) or visual depictions of benefits or positive imagery during the presentation of the major statement in TV ads.

The intention is that the major statement should not be presented in a bland manner that will disengage the audience. The FDA acknowledges that multiple elements can be used to reinforce risk information; however, the FDA has previously issued Untitled letters for the use of distracting elements when presenting the major statement.

It should be noted that this requirement applies to the portion of the ad presenting the major statement, not to any other part of the ad.

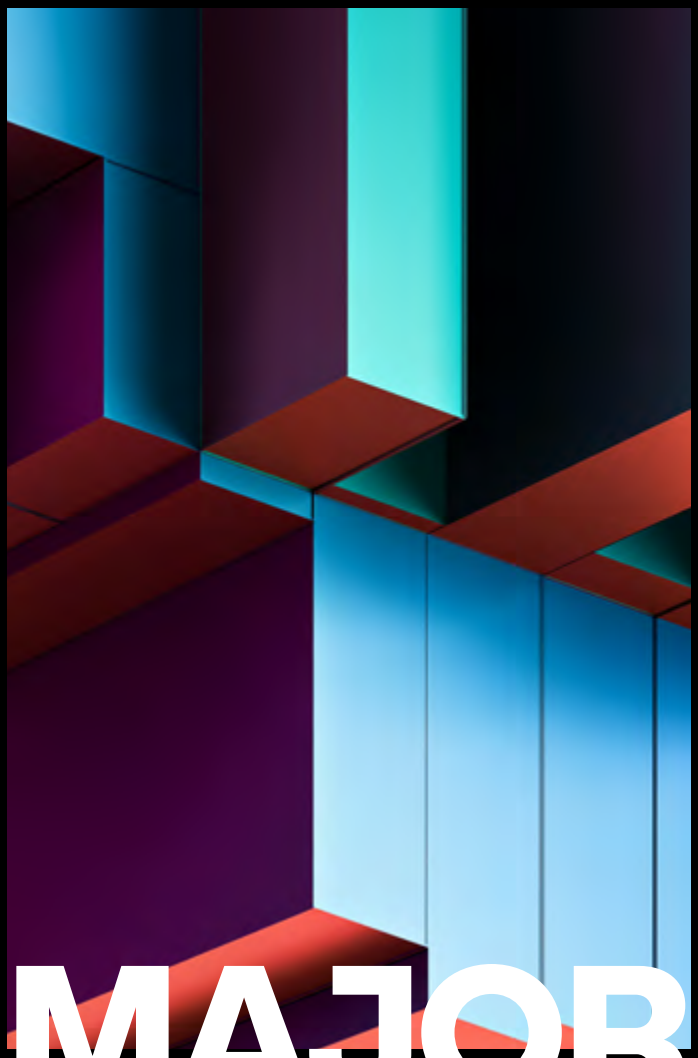
HOW DOES THIS RULING BUILD ON THE PREVIOUS 2010 PROPOSED RULE?

PROPOSED 2010 STANDARD

"The advertisement does not include distracting elements (including statements, text, images, or sounds, or any combination thereof) that detract from the communication of the major statement."

MINOR CHANGES

The final 2023 standard explicitly states that during the presentation of the major statement, the advertisement should not include audio or visual elements that could interfere with comprehension.



MAJOR STATEMENTS IN DTC ADS: A TIMELINE

THE FDA IS FOCUSED ON ENSURING CONSUMERS RECEIVE A TRUTHFUL AND NON-MISLEADING IMPRESSION OF AN ADVERTISED DRUG

With the significant role of DTC TV advertising, which accounted for 75% of the DTC ad spend in 2020, the FDA has reinforced its commitment to ensuring consumers receive accurate and non-misleading information about promoted drugs.[1] Recognizing the pivotal role of DTC advertising in influencing consumers to seek more information about a drug or discuss advertised drugs with their healthcare provider, the FDA emphasizes the importance of ensuring consumers are better informed when they make healthcare decisions.

THE ROLE OF MAJOR STATEMENTS IN DTC ADS

Central to this objective is the FDA's guidance regarding the major statement of side effects and contraindications.[2,3] The FDA originally presented their proposed rule around the presentation of the major statement in DTC TV and radio ads in a CCN manner on March 29, 2010. The standards outlined in the proposed rule were developed based on standards developed by other federal agencies, such as the Federal Trade Commission (FTC), that aim to ensure that disclosures are effectively presented to avoid misleading or deceiving consumers, with common themes such as ease of comprehension, formatting and location of textual information, audio considerations such as pacing and volume, and absence of distracting elements.

THE MAJOR STATEMENT

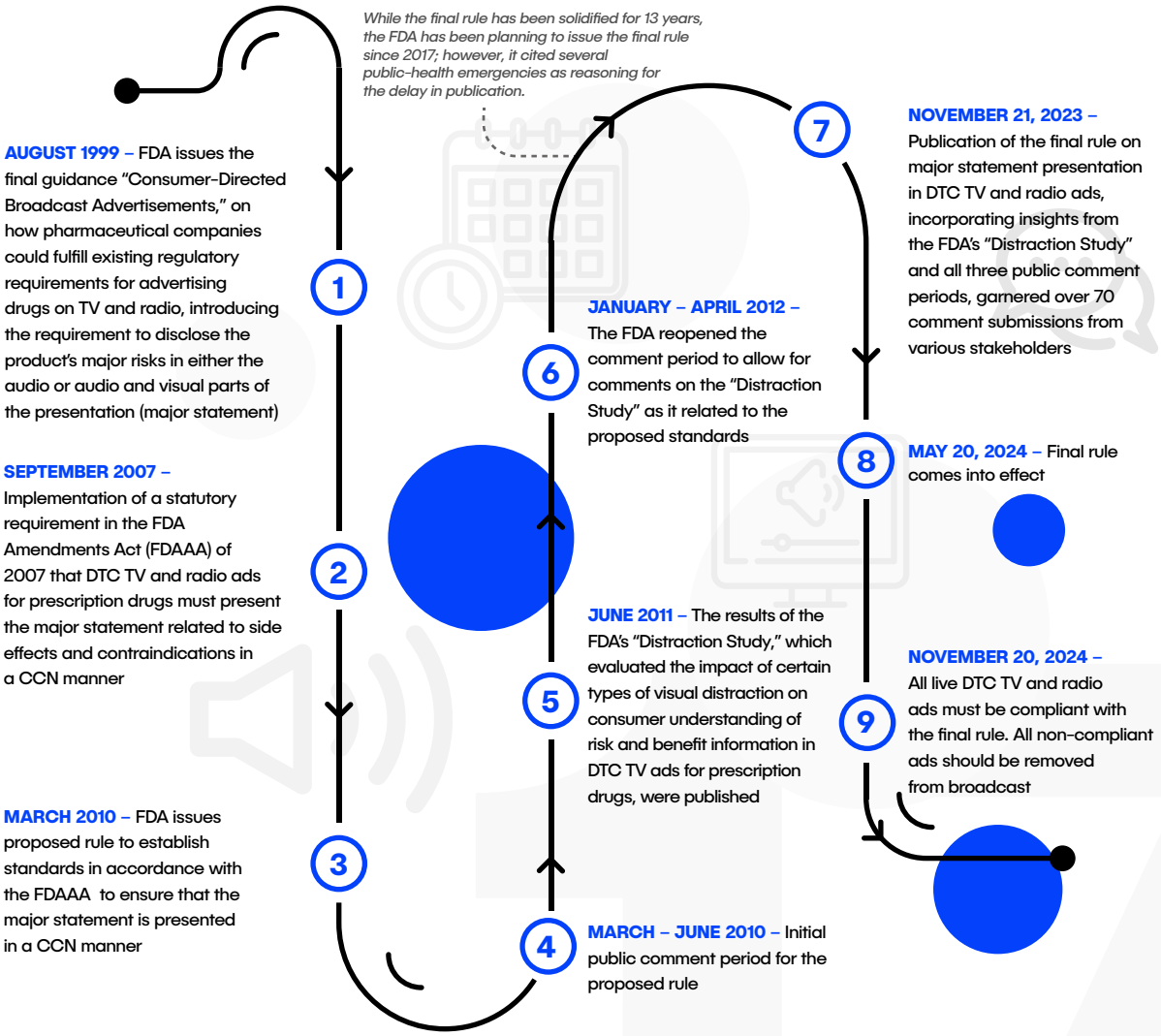
A selected presentation of side effects and contraindications, *not* an exhaustive list of all risks.

The major statement, typically appearing at the middle or end of a DTC TV or radio ad, provides a balanced view of the drug being advertised, ensuring that the consumer is well aware of the most important risks associated with the drug being advertised.

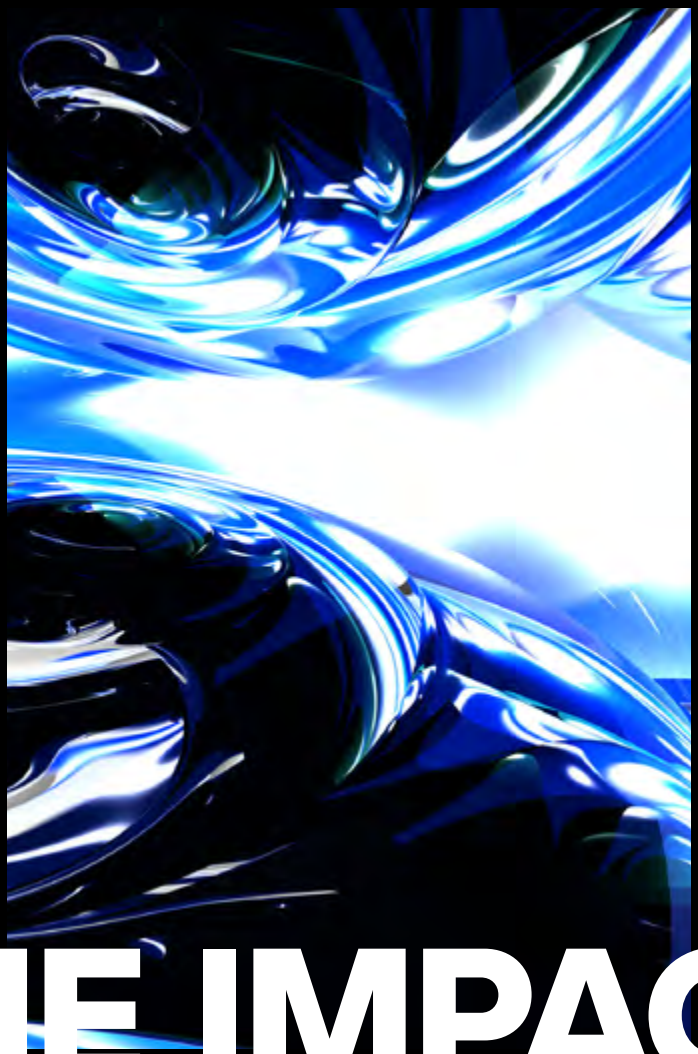
Because risks vary from product to product, the amount of information disclosed within a major statement will vary.

THE MUCH ANTICIPATED FINAL RULE IS OVER A DECADE IN THE MAKING, BUT THE FDA'S MOTIVATION REMAINS THE SAME—IMPROVING CLARITY AND COMPREHENSION OF MAJOR STATEMENTS IN DTC ADS WITHOUT CHANGING THEIR CONTENT

In the March 2010 proposed rule, the FDA presented four standards, including consumer-friendly language, understandable audio information, readable text, and the absence of distracting audio or visual elements. A potential fifth standard, simultaneous presentation in audio or visual portions of the ad, was open for public comment.



Importantly, the introduction of this final rule does not change the content of a major statement—only how it is presented within the context of DTC TV and radio ads.



THE IMPACT OF THE FINAL RULE

THE IMPACT ON DTC TV AND RADIO MAJOR STATEMENT PRESENTATION VARIES

Given minor changes to the original four proposed standards intended to provide clarity, the introduction of the dual modality standard is likely to impact major statement presentation more significantly than the others.

SCENARIO 01

The supers in the major statement are verbatim to the voiceover (VO)

VO: Serious side effects of DrugX include nausea, vomiting, diarrhea, constipation, and headache.

SUPER: Serious side effects of DrugX include nausea, vomiting, diarrhea, constipation, and headache.

—

There is **minimal** to no **impact** on the content or presentation of the major statement.

NEXT STEPS: Ensure compliance by reviewing the major statement against all five finalized standards.

SCENARIO 02

The major statement is *only* presented in the VO—there are no supplementary supers

VO: Serious side effects of DrugX include nausea, vomiting, diarrhea, constipation, and headache.

—

There is a **moderate impact** on the presentation of the major statement.

It is not expected that there will be any changes to the content and/or length of the major statement.

NEXT STEPS: Major statements will need to be updated to comply with the dual modality standard:

- Supers displaying a complete transcript or verbatim key terms/phrases from the VO will need to be added
- Supers will need to be displayed in line with the VO to ensure they are onscreen for a sufficient duration of time

Major statements should also be reviewed against the other four finalized standards to ensure compliance.

Due to changes to the presentation of the major statement, FDA preclearance* may be recommended.

All DTC TV and radio ads must be compliant by November 20, 2024—all non-compliant ads will need to be removed from broadcast. Preclearance* needs, media buys, and timing for removal or updating of DTC TV ads should be considered in timelines.

SCENARIO 03

The supers in the major statement differ from the VO (i.e., they present information complementary to the audio presentation)

VO: Serious side effects of DrugX include nausea, vomiting, diarrhea, constipation, and headache.
SUPER: This is not an exhaustive list of the possible side effects. Talk to your doctor.

—

There is a **major impact** on the content and presentation of the major statement.

This may result in an increased length of the major statement, which will impact the totality of and length of the DTC TV ad.

NEXT STEPS: Major statements will need to be updated to comply with the dual modality standard:

- The major statement will require revisions to include all relevant major side effects and contraindications that may have been previously dispersed across the VO and supers
- Supers need to display a complete transcript or verbatim key terms/phrases from the VO
- Supers will need to be displayed in line with the VO to ensure they are onscreen for a sufficient duration of time

Major statements should also be reviewed against the other four finalized standards to ensure compliance.

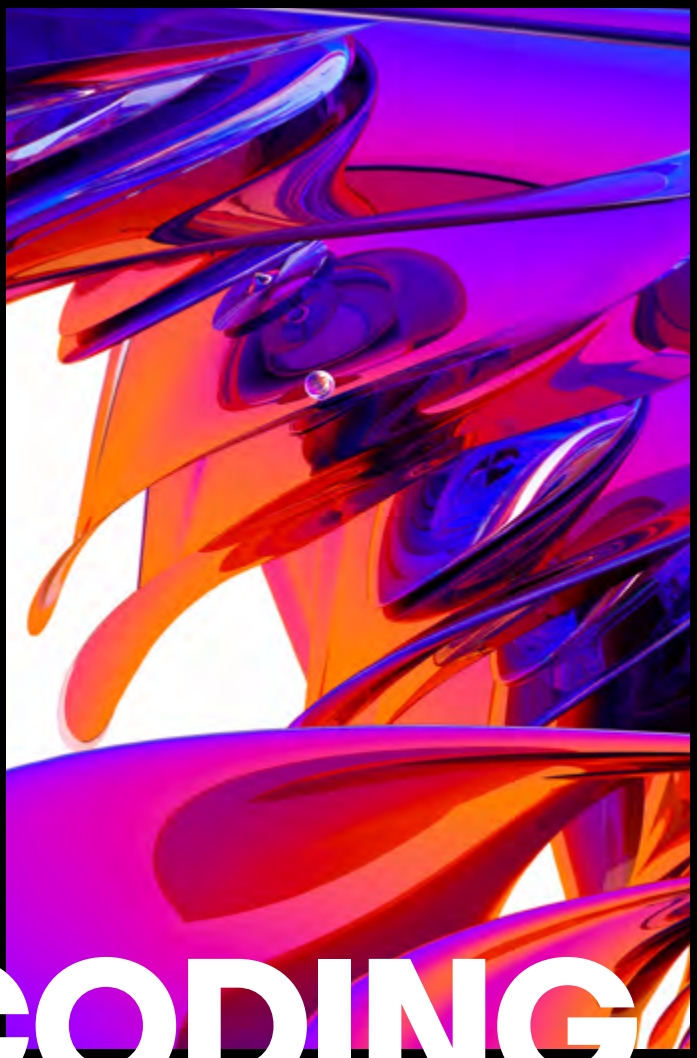
Due to changes to the content and presentation of the major statement, FDA preclearance* is strongly recommended.

*IF SUBSTANTIAL REVISIONS HAVE BEEN MADE TO YOUR MAJOR STATEMENT, YOU MAY NEED TO CONSIDER PRECLEARANCE

In order for the FDA to provide feedback on the major statement, preclearance should occur for initial TV ads and the first TV ad after a label update affecting the Boxed Warning, Contraindications, and/or Warnings & Precautions section(s); preclearance should also be considered if substantial revisions have been made to the major statement outside of these scenarios.[4] This excludes REMS and Schedule II drugs, which must have all DTC TV ads precleared by the FDA regardless if there are material changes to the major statement.

The following should be considered when submitting for preclearance of major statements[4,5]:

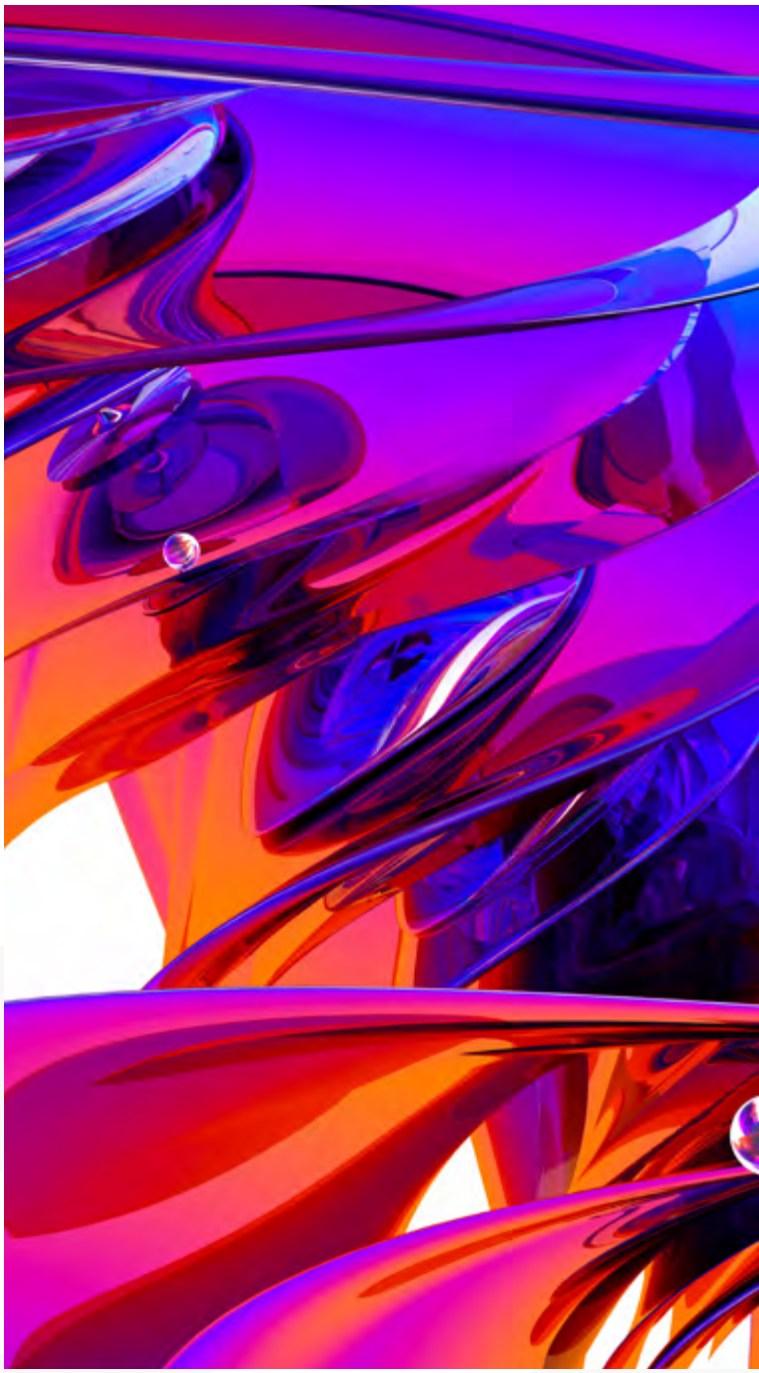
- If submitting prior to May 20, 2024 (the effective date of the final rule), a request for FDA feedback, based on the CCN final rule in the cover letter, must be included
- A note indicating whether the ad is new or a revised version that was already submitted on Form FDA-2253, indicating the original 2253 date if applicable, must be in the cover letter
- If submitting a request for comments, the FDA recommends the submission of the proposed DTC TV and radio ads in their entirety rather than only the major statement
- As we know, preclearance has a 45-day review period, starting when CDER/CBER receives a full submission packet



DECODING FDA COMPLIANCE TOGETHER

DECODING FDA COMPLIANCE WITH STRATEGIC REGULATORY INSIGHT

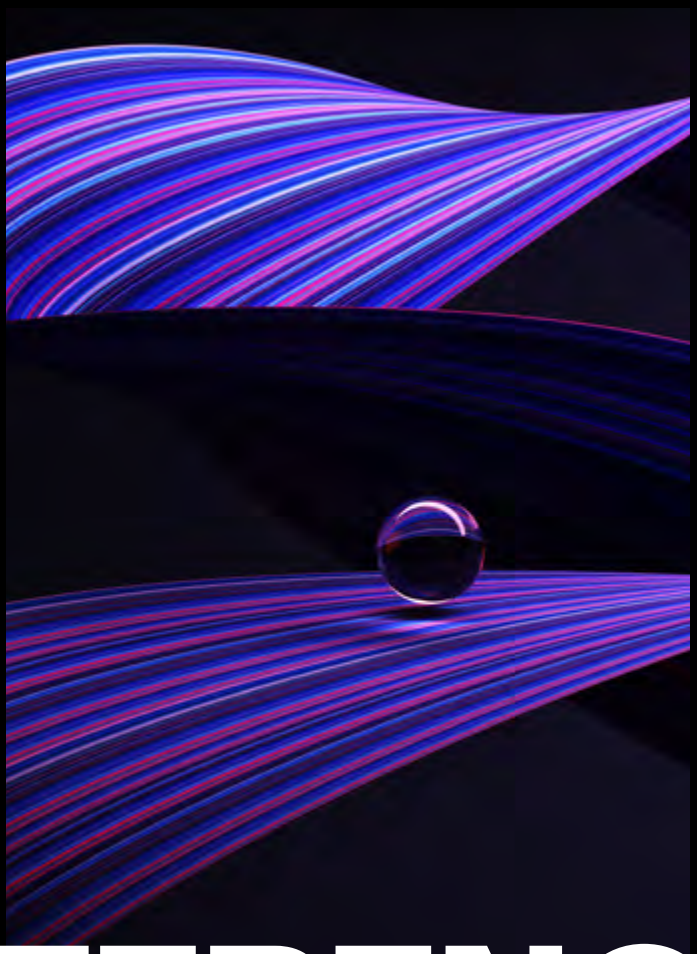
At Klick Health, our Science + Regulatory team plays a critical role in ensuring that all advertising and promotional materials for prescription drugs comply with FDA regulations, working with you to safeguard our clients and consumers alike, and this final guidance is no exception. Our team's expertise ensures that the integrity of the information shared with the public upholds the highest level of accuracy and reliability, maintaining Klick's standard of excellence in every project we undertake.



FURTHER READING

FDA Final Rule for Presenting Major Statements in DTC TV and Radio Ads in a Clear, Conspicuous, and Neutral Manner: https://www.federalregister.gov/documents/2023/11/21/2023-25428/direct-to-consumer-prescription-drug-advertisements-presentation-of-the-major-statement-in-a-clear

FDA Economic/Regulatory Impact Analysis of Final Rule: https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/direct-consumer-prescription-drug-advertisements-presentation-major-statement-clear-conspicuous-and



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REFERENCES

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Take the next step in navigating the regulatory landscape. Reach out to our team for a bespoke strategy session.

Michael Chambers
SVP, Opportunity Creation
mchambers@klick.com