

Rx Drug Promotion and the Clear, Conspicuous, and Neutral Final Rule



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Disclaimer

- This presentation reflects the views of the author and should not be construed to represent FDA's views or policies.

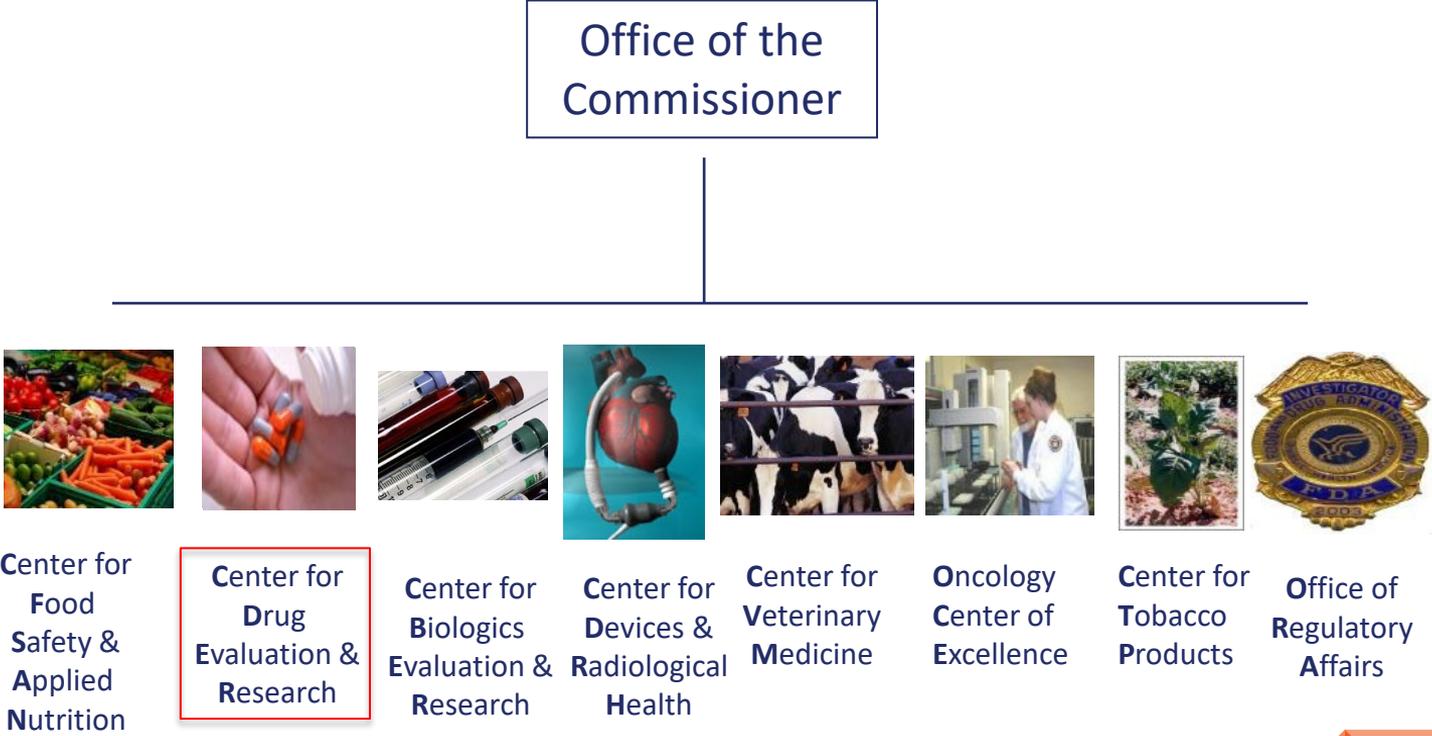
Agenda

- Background
 - OPDP
 - Regulatory Authority
 - Promotional Communications
- Clear, Conspicuous and Neutral (CCN) Final Rule
 - Statutory Driver
 - Background
 - Effective/compliance dates
 - CCN Final Rule Standards
- FDA Assistance
- Questions

The slide features decorative geometric patterns. On the left, a vertical column of triangles in various shades of blue and dark blue. On the right, a vertical column of triangles in various shades of orange and light orange. The word "BACKGROUND" is centered in a large, bold, dark blue font.

BACKGROUND

FDA Organization



OPDP's mission

- Protect the public health by helping to ensure that Rx drug promotion is **truthful, balanced, and accurately communicated**.
- This is accomplished through comprehensive surveillance, compliance, research, and education programs, and by fostering better communication of labeling and promotional information to both healthcare providers and consumers.

FDA Role



- Misconception: FDA “legalized” Direct-to-Consumer (DTC) advertising in the late 1990’s
 - Not true: Nothing in FD&C Act prohibits advertising prescription drugs to consumers

FDA Role cont'd

- Misconception: FDA does not allow drugs with serious side effects to be advertised on TV to consumers
 - Not true: There is no such limitation.

FDA Role cont'd

- Misconception: FDA has the authority to ban DTC advertising
 - Not true: Would require Congressional action and would need to meet Constitutional standards

FDA Role cont'd



- Misconception: FDA approves ads
 - Not true: FDA does not approve ads, but there are some requirements for FDA to receive or options for FDA to review draft ads before they are used.

FDA Role cont'd

- Misconception: FDA regulates “good taste”
 - Not true: FDA focuses on whether advertising and promotional labeling is truthful and not misleading with a particular focus on representations about safety and effectiveness

REGULATORY BACKGROUND

Key Regulatory Principles



- In general, under Federal Food Drug and Cosmetic Act (FD&C Act) and implementing regulations, among other things,

Prescription drug promotion **must** . . .

- Not be false or misleading about a drug's safety or effectiveness
- Have a balance between effectiveness and risk information
- Reveal material facts about the product being promoted, including facts about consequences that result from the use of the drug

Submission of Promotional Materials



- Post-Approval Regulations located in 21 CFR 314.81(b)(3):
 - Require the submission of all promotional materials at the time of initial dissemination or publication
 - Must include Form FDA-2253 and current prescribing information (PI)

What does OPDP regulate?



- Prescription drug advertising and promotional labeling (promotional communications), regardless of audience, including:
 - TV and radio commercials
 - Sales aids, journal ads, and patient brochures
 - Drug websites, e-details, webinars, and email alerts

Categories of Promotional Communications



Product Claim

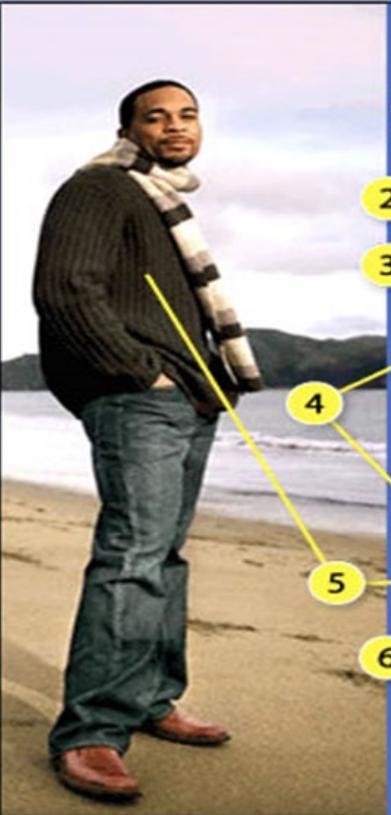
Reminder

Help-seeking
Institutional

Fictitious Examples

- **Drug:** Arbitraer (misvastatium) 100 mg tablets
- **Firm:** ACE Pharmaceuticals
- **Indication:** To treat seasonal allergy symptoms in adults

Product Claim



1 **Arbitraer**
(misvastatium) 100mg tablets

2 **Help Relieve Seasonal Allergy Symptoms**

3 Arbitraer is a prescription medicine that helps control seasonal allergy symptoms, like runny nose, sneezing, and itchy, watery eyes. By taking Arbitraer, **once a day** you can relieve your allergy symptoms for up to 24 hours.

4 You may begin to experience relief of allergy symptoms 2 hours after taking Arbitraer.

5 You may experience headaches, cold symptoms, coughing, or backaches while using Arbitraer.

6 Arbitraer is for use in adults 18 and older. Arbitraer is not for use in children.

7 See reverse for important information about Arbitraer.

8 Ask your doctor if Arbitraer is right for you.

9 **ACE**
Pharmaceuticals
800-555-5555 www.arbitraer.com

This advertisement is entirely fictional—no connection between "Arbitraer/misvastatium" and any real company or product is intended, expressed, or implied.

Reminder



1 *Ask Your Doctor About*

2 **Arbitraer**
(*misvastatium*)

This advertisement is entirely fictional—no connection between "Arbitraer (misvastatium)" and any real company or product is intended, expressed, or implied.

Help-Seeking or Disease Awareness

1

2

Runny Nose?
Sneezing?
Itchy, Watery
eyes?

You may be suffering from
Seasonal Allergies

3 There is help.
Ask your healthcare provider for more information.

4

drug co.

This advertisement is entirely fictional: no connection between "Artisiner (generic name)" and any real company or product is intended, expressed, or implied.

ACE
Pharmaceuticals

Seasonal
allergies

Institutional

Product Claim Communications

- Include representations or suggestions relating to the promoted drug product
 - Must not be false or misleading
 - Must reveal material facts about the product being promoted, including facts about consequences that may result from the use of the drug
 - Must include a balanced risk and efficacy presentation (“fair balance”)

Product Claim Communications cont'd . . .



- Must be accompanied by
 - Prescribing information (for promotional labeling)
 - Brief Summary of information relating to effectiveness, side effects and contraindications (for advertising)
 - for ads in TV/radio format, must include “major statement” of risks with either adequate provision of package labeling or brief summary

FD&C Act before amendment



- FD&C Act section 502(n) requires that all Rx drug advertising include “true statement of . . . such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations”

21 CFR 202.1 Before CCN Final Rule



- Implementing regulations at 21 CFR 202.1(e)(1) required that:
 - ads for Rx drugs (veterinary and human)
 - broadcast through media such as radio, TV, or telephone communications systems
 - *shall include information relating to major side effects and contraindications of the advertised drug in audio or audio and visual parts of presentation (aka “major statement”)*

Statutory Driver

- Food and Drug Administration Amendments Act of 2007 (FDAAA) amended FDCA section 502(n) by adding:

“In the case of an advertisement for a drug subject to section 503(b)(1) of this title presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner.”

FDAAA Directive to FDA



- FDAAA also directed FDA to establish standards to determine whether a major statement is presented in a clear, conspicuous and neutral manner via rulemaking

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CLEAR, CONSPICUOUS, AND NEUTRAL FINAL RULE

CCN Final Rule

- Issued November 21, 2023
- Amends 21 CFR 202.1(e)(1)
- Requires that certain advertisements for human prescription drugs present the major statement relating to side effects and contraindications in a **clear, conspicuous, and neutral manner**
- Establishes standards for CCN manner of presentation

Scope and applicability

- CCN Final Rule applies to advertisements for human prescription drugs that:
 - Are presented directly to consumers (DTC)
 - Are in TV/radio format
 - State the name of the drug and its condition(s) of use

CCN Final Rule Compliance Date



- CCN Final Rule effective date: May 20, 2024.
- Firms have until November 20, 2024 to bring all DTC TV/radio ads subject to CCN into compliance.
- FDA recommends ensuring ads are brought into compliance as soon as possible.

What is the “major statement”?

- The term “major statement” refers to this information about the major side effects and contraindications of the advertised prescription drug(s).
 - It is a selected presentation of the major side effects and contraindications of the drug and may not be a listing of every risk

The CCN Final Rule describes the standards for the *manner of presentation* of the major statement to be considered clear, conspicuous and neutral. The rule does not specify what side effects and contraindications to include in the major statement.

Major Statement: Standards for Presenting in Clear, Conspicuous and Neutral Manner

Major Statement Standard 1

1. It is presented in consumer-friendly language and terms that are readily understandable.

Major Statement Standard 2



2. Its audio information, in terms of the volume, articulation, and pacing, is at least as understandable as the audio information presented in the rest of the advertisement.

Major Statement Standard 3



3. In advertisements in television format, it is presented concurrently using both audio and text (dual modality). To achieve dual modality:

Major Statement Standard 3

cont'd . . .



- a) 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
- b) The text is displayed for a sufficient duration to allow it to be read easily. For purposes of this standard, 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.

Major Statement Standard 4



4. 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.

Major Statement Standard 5



5. 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.

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
 - Use terms likely to be familiar to consumers, not medical jargon.
 - Avoid vague language or terminology

The CCN Final Rule does not require the use of a particular grade level of reading or similar criterion

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 the other information in the ad in terms of volume, articulation, and pacing

One possible way to do this is to compare major statement audio to audio in the rest of the ad

How can firms comply with Standard 3?



- Standard 3 requires that, for TV ads, the major statement is presented concurrently using audio and text (dual modality).

Dual Modality: Prong One

- Text displays verbatim key terms or phrases **or** entire verbatim transcript from corresponding audio; e.g.,
 - “The most common side effects of DrugX are dry mouth, headache and heartburn” or
 - “· dry mouth · headache · heartburn”

Dual Modality: Prong Two

- And text is displayed for sufficient duration to allow it to be read easily. Duration will be considered sufficient if text display begins at the same time and ends at approximately the same time as the corresponding audio.
 - Display of major statement text begins when major statement audio begins and stops at approximately the same time as corresponding audio concludes

Pacing of the audio presentation of the major statement must also enable the ad to satisfy Standard 2.

How can firms comply with Standard 4?



- In TV ads, 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
 - Applies to the major statement presentation, not other text (if any)

Does not require particular font colors or sizes, placement, or backgrounds, but firms must ensure that combination of these text aspects is easily readable

How can firms comply with Standard 5?



- Standard 5 requires that, during the presentation of the major statement, the ad does not include audio or visual elements, alone or in combination, that are likely to interfere with comprehension of the major statement
 - Applies only to the major statement portion of the ad

Does not categorically prohibit use of other creative elements during the major statement

Which CCN standards apply?



- All 5 standards apply to ads in television format that are subject to the CCN Final Rule.
- Standards 1, 2, and 5 apply to ads in radio format that are subject to the CCN Final Rule.

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FDA RESOURCES

CCN resources

- Small Entity Compliance Guide
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/direct-consumer-prescription-drug-advertisements-presentation-major-statement-clear-conspicuous-and>
- CCN Final Rule Frequently asked questions: [OPDP Frequently Asked Questions \(FAQs\) | FDA](#)

Voluntary submission of promotional communications



- Firms may request comments from FDA on proposed DTC TV/radio ads before dissemination.
- Guidance for Industry: [Providing Regulatory Submissions in Electronic and Non-Electronic Format — Promotional Labeling and Advertising Materials for Human Prescription Drugs](#)
 - Center for Drug Evaluation and Research (CDER): Reviewers in Office of Prescription Drug Promotion (OPDP)
 - Center for Biologics Evaluation and Research (CBER): Reviewers in Advertising and Promotional Labeling Branch (APLB)

Additional resources

- OPDP webpage: [The Office of Prescription Drug Promotion \(OPDP\) | FDA](#)
- APLB webpage: [About the Advertising and Promotional Labeling Branch \(APLB\) | FDA](#)

Summary

- The CCN Final Rule amends 21 CFR 202.1(e)(1).
- The CCN Final Rule:
 - Requires that in human prescription drug ads presented DTC in TV/radio format and stating the name of the drug and conditions of use; the major statement (major side effects and contraindications) must be presented in a clear, conspicuous, and neutral manner; and
 - Establishes standards for that CCN manner of presentation
- Compliance Date: November 20, 2024
- OPDP and APLB Review

Questions?

