



# Coffee Labeling: Compliance, Risks, and Opportunities

Presented by Faegre Drinker Biddle & Reath

# Today's Presenter



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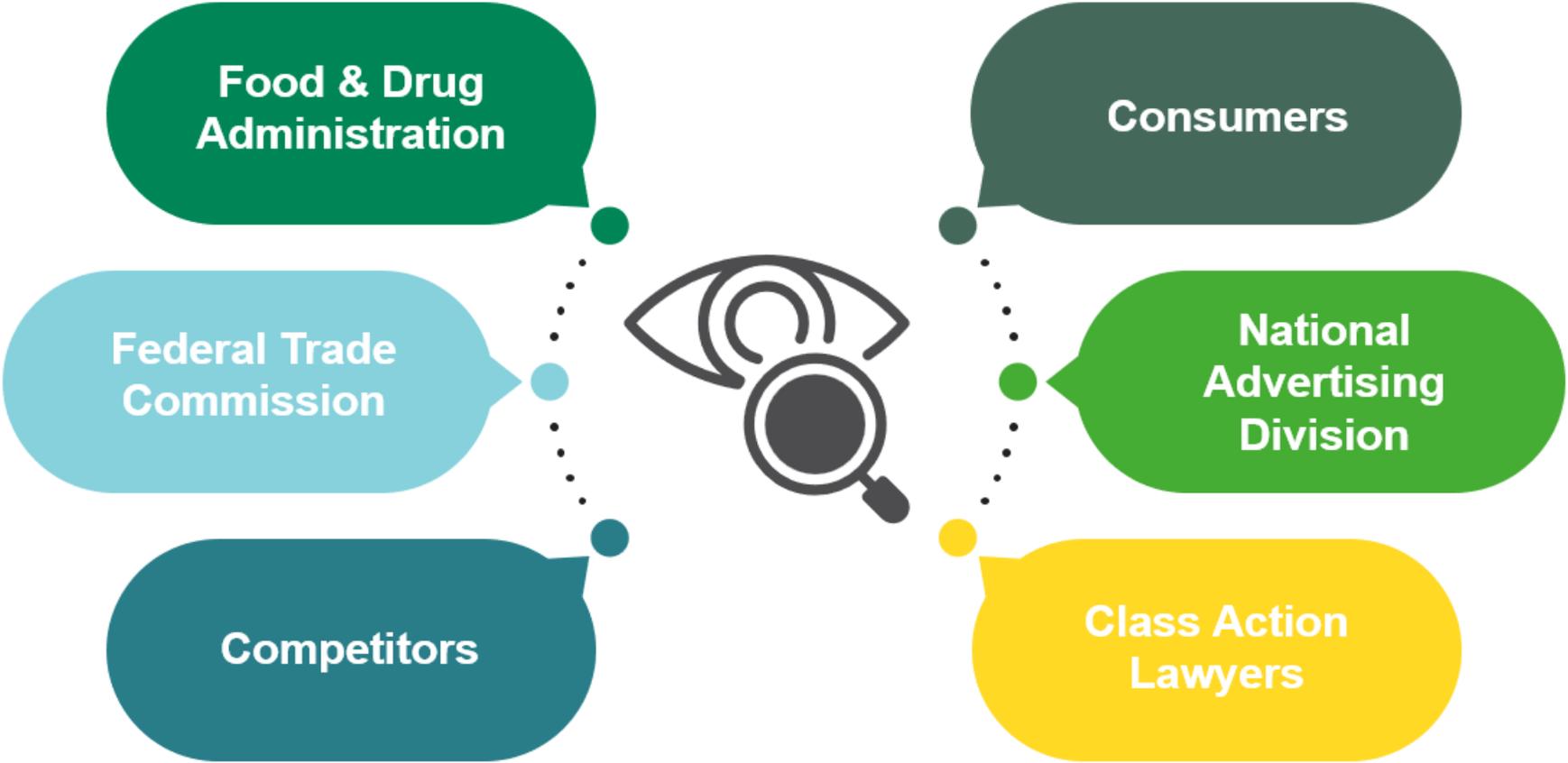


# Agenda

- **Who's Looking at Your Label**
  - Regulators
  - Industry
  - Consumers
- **Voluntary Labeling Claims**
  - Nutrient Content Claims
  - "Healthy"
- **Risk Management Practices**
  - Substantiation
  - Disclosures
  - Guiding Questions



# Who's Looking at Your Labels?



# Federal Regulatory Enforcement



- Assures food is safe and not “misbranded” under the FDCA
  - Labels & labeling cannot be false or misleading
- Most commonly enforced through warning letters but can also seize misbranded products and request voluntary recalls



## FEDERAL TRADE COMMISSION PROTECTING AMERICA'S CONSUMERS

- Advertising must be truthful, not misleading, and adequately substantiated
- Can bring civil actions with penalties of \$50,000+ per violation, send cease and desist letters, and require corrective advertising

## Helpful Regulatory Guidance

- ✓ FDA Food Labeling Guide
- ✓ FTC Green Guides
- ✓ FTC Deception Policy
- ✓ FTC Substantiation Policy



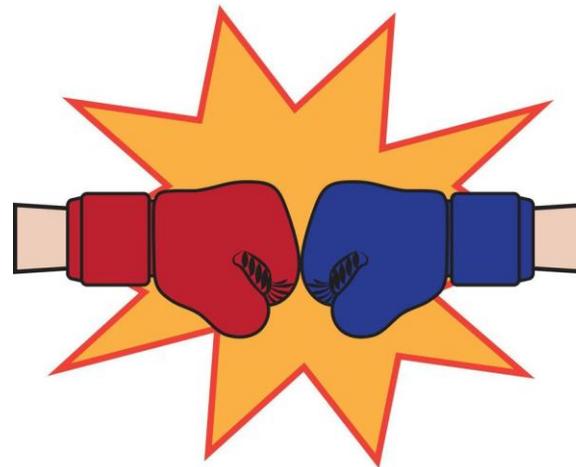
# Self Regulatory



- Independent non-profit that monitors and reviews advertising for truthfulness and accuracy, with a focus on harm to the competitive marketplace.
  - May refer cases to the FTC
- Reviews may be prompted by NAD itself or complaints filed by consumers or competitors.

## Competitors

- Sue in court under the Lanham Act
- File a complaint with the NAD



# Consumer Fraud Class Actions

**Often brought under state consumer protection statutes.**

Monetary damages, injunctive relief, and punitive damages available.

**Plaintiffs allege that the label, which can include both words and pictures, is “deceptive” or “misleading.”**

Plaintiffs allege they wouldn't have bought the product, or paid as much for the product, absent the allegedly deceptive claim.

**Might also challenge claims made on the company's website and any information accompanying the product.**



# Voluntary Labeling Claims

## Regulated Voluntary Claims

- Nutrient content claims
- Structure/function claims
- Relative claims
- Organic
- Made in USA

## Undefined Voluntary Claims

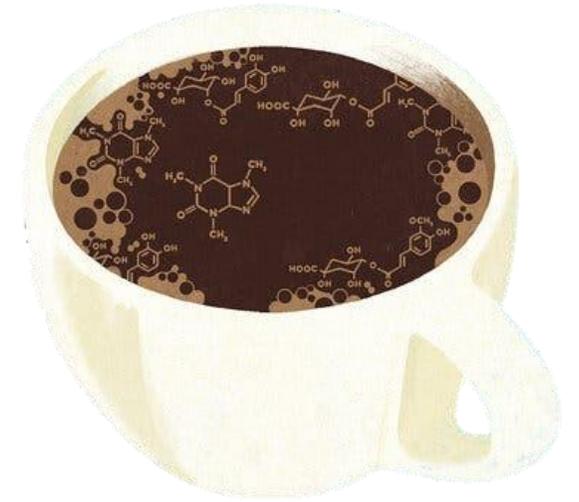
- Third-party certifications
- Origin claims
- Descriptive claims
- Market share claims
- Sensory claims



# Nutrient Content Claims

## Characterize the level of nutrients in a product

- **Express**
  - Direct statement about the level (or range) of a nutrient
- **Implied**
  - Describes the food or an ingredient in a manner that suggests that a nutrient is absent or present in a certain amount
  - Suggests that a food may help consumers maintain healthy dietary practices due to its nutrient content, where there is also implied or explicit information about the nutrition content of the food



# Background on “Healthy” Claims

- **September 2022:** The FDA proposed changes to the definition of “healthy,” specifically asking if certain foods meeting the definition of calorie free, such as coffee, should qualify as “healthy.”
- **December 2024:** The FDA issued final rule updating the requirements for labeling and marketing foods as “healthy” and providing specific parameters around the use of the term to describe coffee.
- **April 2025:** Final rule effective
- **February 2028:** Compliance deadline

**Food Labeling: Nutrient Content Claims; Definition of Term  
“Healthy”**

A Rule by the Food and Drug Administration on 12/27/2024



# Implied Nutrient Content Claim: “Healthy”

- 21 CFR 101.65(d)(3)
- **“Healthy”** may be used on the label or in the labeling of foods that are useful in creating a diet that is consistent with dietary recommendations and meet certain criteria

## Includes Derivative Terms

- ✓ “health”
- ✓ “healthful”
- ✓ “healthfully”
- ✓ “healthfulness”
- ✓ “healthier”
- ✓ “healthiest”
- ✓ “healthily”
- ✓ “healthiness”

# “Healthy” Coffee

Coffee (including whole, ground, and roasted coffee beans) and coffee products (including flavored, decaffeinated, and soluble coffee) may be labeled as “healthy” if it:

- ✓ Has **fewer than 5 calories** per 12-ounce Reference Amount Customarily Consumed (RACC); **and**
- ✓ Has **fewer than 5 calories** per labeled serving.

✓ < 5 cal.      X ≤ 5 cal.      X > 5 cal.

# Calories Per Serving



Because the DGA recommend that consumers primarily drink calorie-free beverages, the FDA looked to its existing definition of **calorie free**, which describes foods containing less than 5 calories per RACC and per labeled serving

- Less about nutritional and health benefits of coffee and more about calorie intake

# Labeled Serving Size

- **Both** the RACC **and** the labeled serving size must have fewer than 5 calories per serving.
- The RACC for coffee, including flavored or sweetened, is 12 fluid ounces (360 mL).
- Certain coffee products might have a different serving size, e.g., single serve drinks.

# Nutrition Facts Panel

- Historically, many coffee products with insignificant amounts of certain nutrients were exempt from the NFP requirement.
  - Exception to the exemption when the label or labeling includes nutrient claims or other nutrition information.
- Because “healthy” is an implied nutrient content claim, the NFP exemption does not apply.
  - FDA exercising enforcement discretion.
  - Information in NFP confirms that the labeled serving size and calorie content meet the requirements.



**Nutrition Facts**  
37 servings per container  
Serving size 6 fl.oz. (9g) coffee

Amount per serving	% Daily Value*
<b>Calories</b>	<b>0</b>
<b>Total Fat</b> 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	0%
<b>Cholesterol</b> 0mg	0%
<b>Sodium</b> 0mg	0%
<b>Total Carbohydrate</b> 0g	0%
Dietary Fiber 0g	0%
Total Sugars 0g	0%
Includes 0g Added Sugars	0%
<b>Protein</b> 0g	0%
Vitamin D 0mcg	0%
Calcium 0mg	0%
Iron 0mg	0%
Potassium 2mg	0%

\*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.



**Nutrition Facts**  
24 Servings Per Container  
Serving Size 2 Tbsp (12g)

Amount Per Serving	% Daily Value*
<b>Calories</b>	<b>0</b>
<b>Total Fat</b> 0g	0%
<b>Sodium</b> 0mg	0%
<b>Total Carbohydrate</b> 0g	0%
Dietary Fiber 0g	0%
Total Sugars 0g	0%
Includes 0g Added Sugars	0%
<b>Protein</b> 0g	0%

Not a significant source of saturated fat, trans fat, cholesterol, vitamin D, calcium, iron, and potassium.  
\*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Ingredients: Arabica coffee\*, vanilla powder, organic ground cinnamon.

# Recordkeeping

- Coffee is exempt from formal recordkeeping requirements for the “healthy” claim.
- But FDA requires manufacturers to ensure the validity of a product label’s stated nutrient information.
  - Third-party testing
  - USDA Nutrient Database

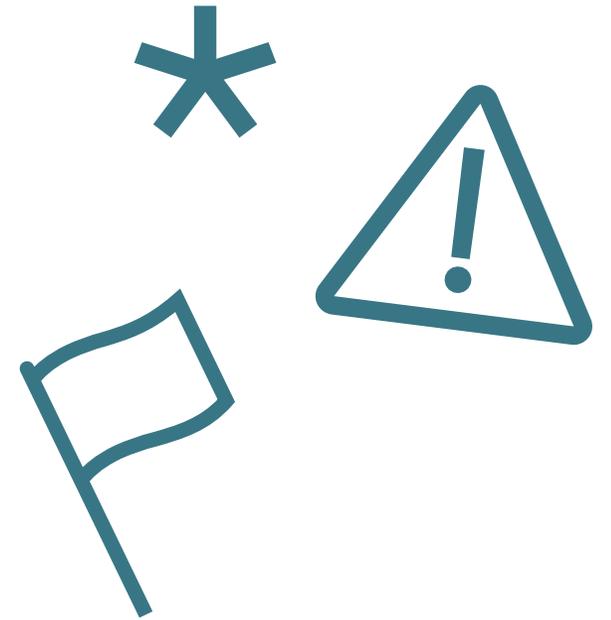


# Recordkeeping & Risk Management

- Labeling claims should be supported by adequate substantiation.
  - **Reasonable basis** showing that claims are truthful and not misleading
  - **Direct** support
    - Facts, studies, scientific sources, government guidance, etc. that have a strong supporting relationship to the claim
  - Exists **before** making the claim
  - Substantiation file should **stand alone** without requiring references to outside materials
  - **Competent** and **reliable** evidence
    - Nature of the claim determines amount and type of substantiation required

# Managing Risk through Disclosures

- When appropriate, use an asterisk to signal that a claim is qualified and include a disclosure.
- Qualifying language should be clear and conspicuous so that consumers actually notice and understand it.
- Disclosures and fine print cannot correct an affirmatively misleading representation.
  - Disclosure should explain the claim, not contradict it.
  - Courts only consider back label statements when the front label is ambiguous.



# Other Ways to Manage Risk

- Review labels for regulatory compliance **and** litigation risk
- Before making a claim, ask:
  - What do I want the consumer to think when reading this claim?
  - What evidence do I have to support this claim?
  - Can I tie this claim back to a specific practice and/or data point?
  - Could this claim be more specific?
  - Could this claim have any unintended implied meanings?
  - Is a disclosure required to convey the intended meaning?
  - How does the rest of the label impact the meaning of this claim?
  - Has the FDA sent warning letters regarding this type of claim?
  - Has this type of claim been the subject of consumer fraud litigation?
  - Would a competitor dispute this claim?



A close-up, shallow depth-of-field photograph of coffee beans. The beans are dark brown and roasted, with some showing a lighter, golden-brown hue. They are scattered across the frame, with some in sharp focus and others blurred in the background. The word "Questions?" is written in a clean, white, sans-serif font, centered horizontally and slightly above the vertical center of the image.

Questions?

**Thank you!**



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