



Food Labeling

Nutrient Content, Health, and Other Claims

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Agenda

1. Why do we care?
2. Framework
3. Nutrient Content Claims
4. Health Claims
5. Structure/Function Claims
6. Other Claims: "Natural," "Organic,"
"Gluten Free," "Non-GMO"

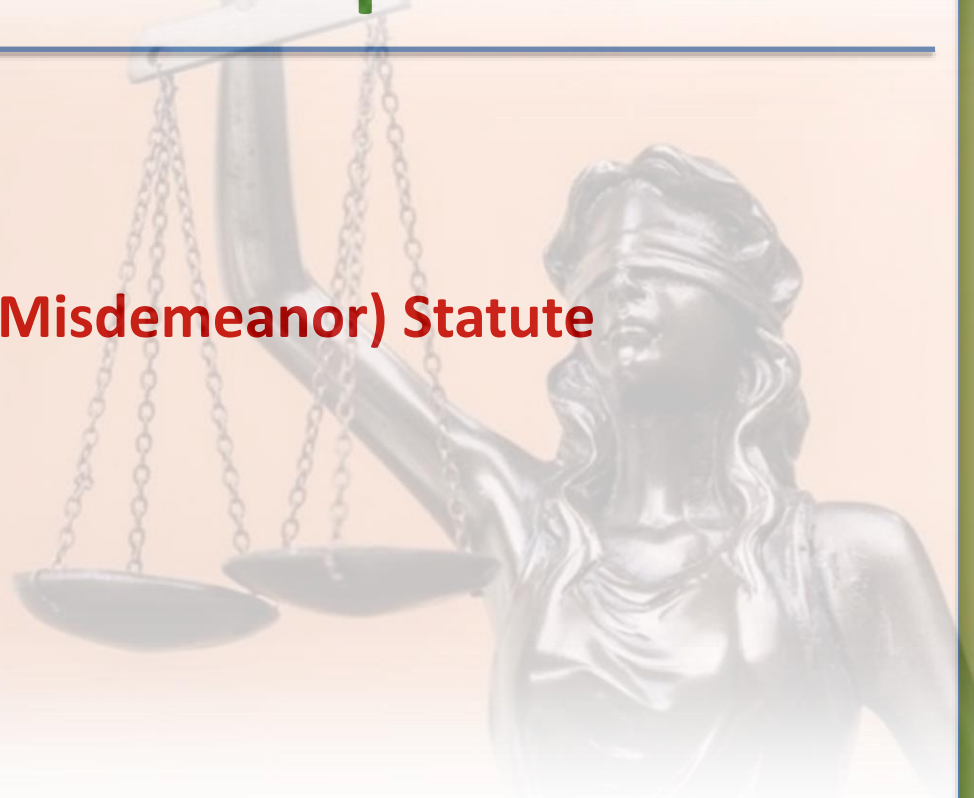
POLLING QUESTION

- Reasons Why Companies Should Care?



Why ~~Do We~~ Should Companies Care?

- Love of truth?
- **FDCA: A Strict Liability (Misdemeanor) Statute**
- Costs of correction
- Reputational costs
- ***Civil liability***



Framework

Labeling is defined as all labels *and* other written, printed, or graphic matters "accompanying" an article at any time while such article is in interstate commerce or held for for sale after shipment or delivery in interstate commerce.



Product
Labels



Sales
Sheets



Advertising



Website



Social
Media



Other
Links

Framework

- ***Misbranding*** is the context
- **False and Misleading**



A material misrepresentation or omission likely to mislead consumers acting reasonably under the circumstances.

Framework

- ***Misbranding*** is the context
- **False and Misleading**
- How do I misbrand thee?
 - Incorrectly named food
 - Imitation of another food
 - Missing label bits
 - Misleading fill
 - Unlabeled flavors, colors, preservatives
- **"CLAIMS"**



POLLING QUESTION

- What's Missing?



Product
Labels



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Website

Framework

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Product
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Types of Claims

- **Claim**

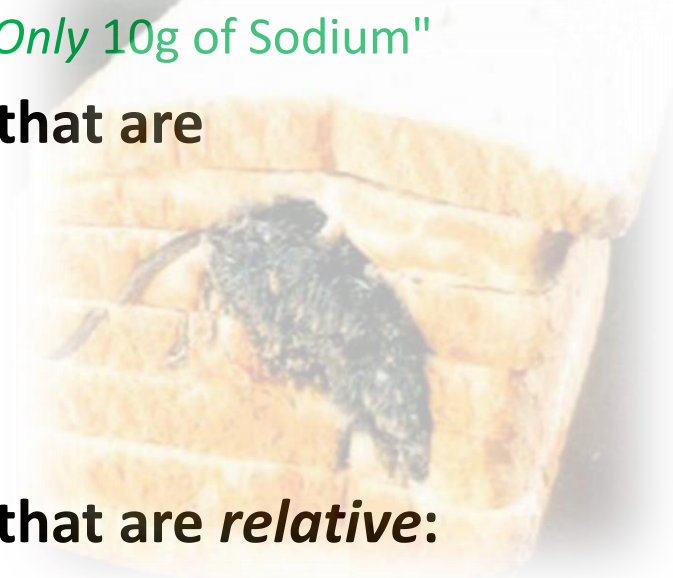
- *Def.* "An assertion that something is true" (OED)
- {From Latin *clamare*: "call out"}

- Express v. Implied
- Commissions and Omissions

- Nutrient content
- Health
- Other

Nutrient Content Claims

- **CRITICAL Distinction: Fact vs. Characterization**
 - "10g Sodium" vs. "Low Sodium" or "*Only* 10g of Sodium"
- **Examples of express content claims that are *absolute*:**
 - "High"
 - "Low"
 - "Good source"
- **Examples of express content claims that are *relative*:**
 - "Less"
 - "More"



Nutrient Content Claims

Express (absolute)

A Food Labeling Guide

Guidance for Industry

U.S. Department of Health
and Human Services

Food and Drug Administration
Center for Food Safety and Applied Nutrition

January 2013

Free

Synonyms for
“Free” “Zero”,
“No”, “Without”,
“Trivial Source
of”, “Dietarily
Insignificant
Source of”

Definitions for
“Free” for meals
and main dishes
are the stated
values per
labeled serving
but are not
defined for
calories

Low

Synonyms for
“Low”:
“Little”, (“Few”
for Calories),
“Contains a
Small Amount
of”, “Low Source
of”

Claim

Requirements

“High,” “Rich In,”
or “Excellent Source
Of”

Contains 20% or more of the DV per RACC. May
be used on meals or main dishes to indicate that the
product contains a food that meets the definition, but
may not be used to describe the meal. *21 CFR 101.54(b)*

“Good Source,”
“Contains,” or
“Provides”

10%-19% of the DV per RACC. These terms may be
used on meals or main dishes to indicate that the
product contains a food that meets the definition but
may not be used to describe the meal. *21 CFR 101.54(e)*

Nutrient Content Claims

Example: Calories

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Nutrient	Free	Low	Reduced/Less	Comments
Calories 21 CFR 101.60(b)	Less than 5 cal per RACC and per labeled serving (b)(1)	40 cal or less per RACC (and per 50g if RACC is small) (b)(2) Meals and main dishes: 120 cal or less per 100 g (b)(3)	At least 25% fewer calories per RACC than an appropriate reference food (for meals and main dishes, at least 25% fewer calories per 100 g) Reference food may not be "Low Calorie" Uses term "Fewer rather than "Less (b)(4) & (5)	"Light" or "Lite": if 50% or more of the calories are from fat, fat must be reduced by at least 50% per RACC. If less than 50% of calories are from fat, fat must be reduced at least 50% or calories reduced at least 1/3 per RACC 21 CFR 101.56(b) "Light" or "Lite" meal or main dish product meets definition for "Low Calorie" or "Low Fat" meal and is labeled to indicate which definition is met 21 CFR 101.56(d) For dietary supplements: Calorie claims can only be made when the reference product is greater than 40 calories per serving 21 CFR 101.60(a)(4)

POLLING QUESTIONS

- **"Healthy": Fact or Characterization?**
- **"Healthy": Express or Implied?**

Nutrient Content Claims

- **CRITICAL Distinction: Fact vs. Characterization**
 - "10g Sodium" vs. "Low Sodium" or "Only 10g of Sodium"
- **Examples of express, nutrient content claims:**
 - "High"
 - "Low"
 - "Good source"
- **Healthy: Characterization**
- **Healthy: Implied Nutrient Content Claim**

Nutrient Content Claims

Healthy

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Conditions for the Use of "Healthy"

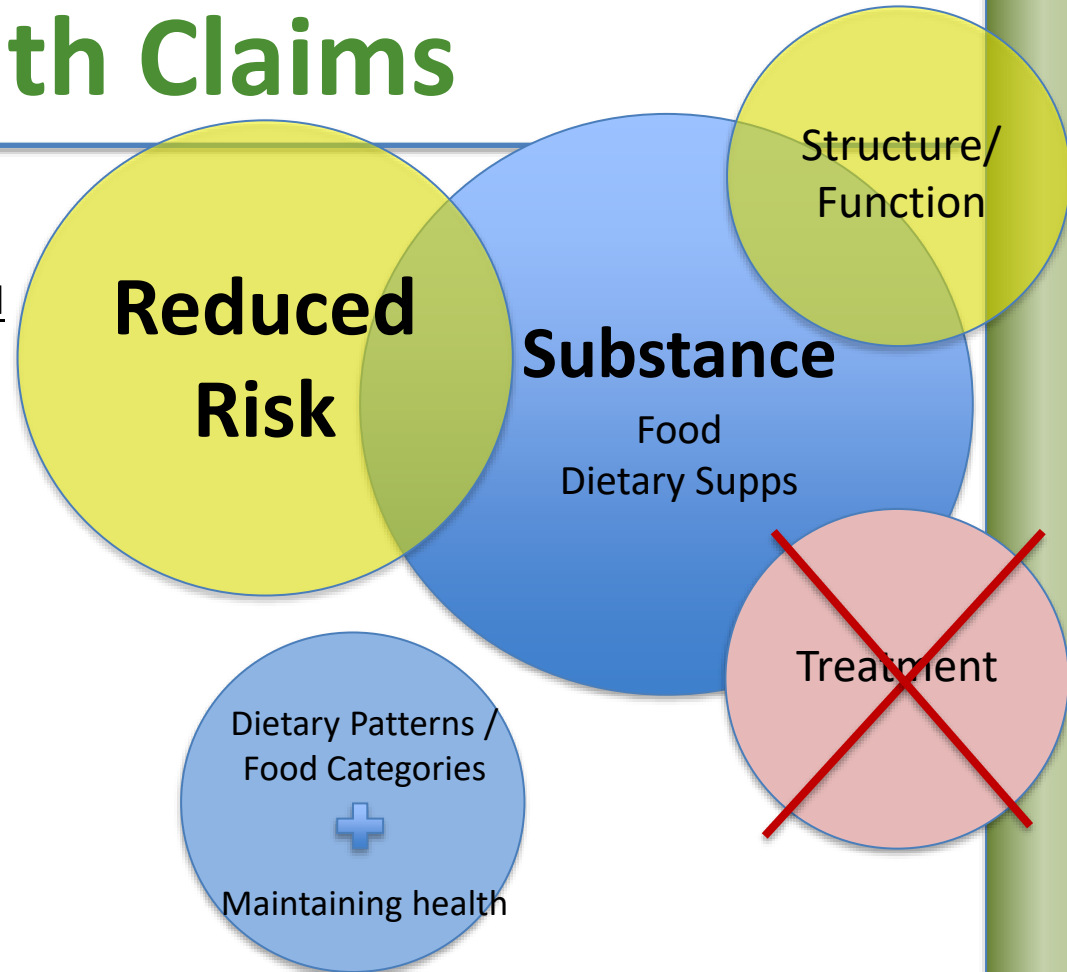
	<i>Individual Food</i>	<i>Seafood/Game Meat</i>	<i>Meal/Main Dish</i>
TOTAL FAT	low fat	< 5 g fat /RACC & /100g	low fat
SATURATED FAT	low sat fat	< 2 g sat fat /RACC & /100g	low sat fat
SODIUM	≤ 480 mg /RACC and / l.s.; or /50 g, if RACC is small	≤ 480 mg /RACC and /l.s.; or /50 g, if RACC is small	≤ 600 mg /l.s.
CHOLESTEROL	≤ disclosure level	< 95 mg /RACC & / 100 g	≤ 90 mg /l.s.
BENEFICIAL NUTRIENTS	Contains at least 10% of DV / RACC for vitamins A, C, calcium, iron, protein, or fiber except: raw fruits and vegetables; or a single ingredient or mixture of frozen or canned fruits and vegetables (may include ingredi- ents whose addition does not change the nutrient profile of the fruit or vegetable); enriched cereal-grain products that conform to a standard of identity in 21 CFR 136, 137, or 139.	Contains at least 10% of DV /RACC for vitamins A, C, calcium, iron, protein, or fiber	Contains at least 10% of the DV /l.s. of two nutrients (for a main dish product) or of three nutrients (for a meal product) of vit. A, vit. C, calcium, iron, protein, or fiber.
FORTIFICATION	Per 21 CFR 104.20	Per 21 CFR 104.20	Per 21 CFR 104.20

Note: l.s. = labeled serving; RACC = Reference Amount Customarily Consumed per Eating Occasion; small RACC = 30 g or less, or 2 tablespoons or less

Health Claims

- **Definition:**
 - Describes the relationship between a substance and reduced risk of disease or health-related condition

Substance + Reduced Risk + Disease or Health Condition



- **Health claim vs. disease treatment**
- **Health claim vs. dietary guidance**
- **Health claim vs. structure / function claim**

Health Claims

- **Justifying Claims**

- Authorized health claims (regulation)
- Authoritative statement of US Government scientific body
- "Qualified" health claims

- **Qualified health claims**

- By petition
- Not supportable by regulation
- *Can be rendered non-misleading by qualifying language*



Health Claims

- **Justifying Claims**

- Authorized ("Approved") health claims (regulation)
- Authoritative statement of US Government scientific body
- "Qualified" health claims

Foods

Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.

Foods

"Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol may reduce the risk of heart disease and some cancers."

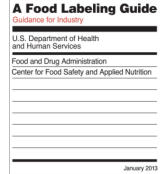
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Foods and Dietary Supps

Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [] gram of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.]

Health Claims



- **Foods must satisfy prescribed requirements, e.g.:**

- **Must be low fat (NCC)**
- **Fish and game meats must be "extra lean"**

Foods

Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.

Structure / Function Claims

"Conventional" Foods

- Foods traditionally understood to be consumed for taste, aroma, or nutritional value.
- S/F claims must be derived from the nutritive value of the food / a nutritive component of the food.

Dietary Supplements

- Dietary supplements are characterized by relying on *dietary ingredients*, which may or may not be nutritive.
- S/F claims may be derived from *non-nutritive* dietary ingredients (e.g., herbal extracts).

Structure / Function claims describe how a food or food ingredient affects the structure or function of the human body.

Structure / Function Claims

	Nutritive	Non-nutritive	Structure/ Function	Health Claim	Treat/prevent/ mitigate disease
Conventional Food	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Dietary Supplement	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Structure / Function Claims

Disease Claim

Effect on a specific disease or class of diseases

Characteristic signs and symptoms of disease

Abnormal conditions of natural state, e.g., menstruation

EXAMPLE

Protects against the development of cancer

Reduces cholesterol
Reduces joint pain

Severe cramping (vs mild, transient cramping)

POLLING QUESTION

- **For our purposes, how are we distinguishing between:**
 - 1. Conventional foods; and**
 - 2. Dietary supplements?**

Structure / Function Claims

"Conventional" Foods

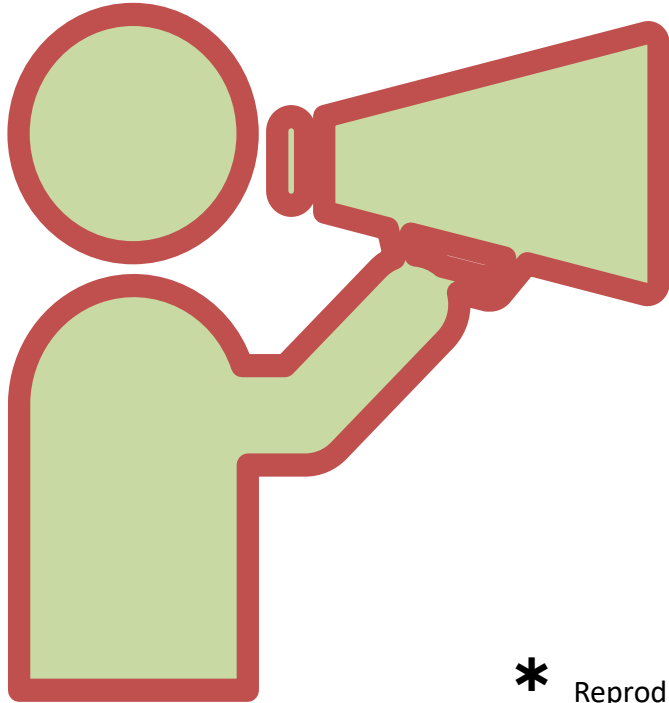
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Other Claims



- **Natural**
- **Gluten Free**
- **Non-GMO / GMO Free**
- **Organic**



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Questions



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