



Legal Roundtable:
*Regulatory
Overview*



Spring Education Series
April 26, 2014
Boulder, Colorado

Primary Regulating Agencies

FTC

- **Approximately 1200 employees**
- **Advertising and marketing, antitrust, privacy and identity protection**



FDA

- **About 25¢ of every consumer dollar**
- **Approximately 15,000 employees (5,000 in enforcement)**
- **About 10¢ is food**



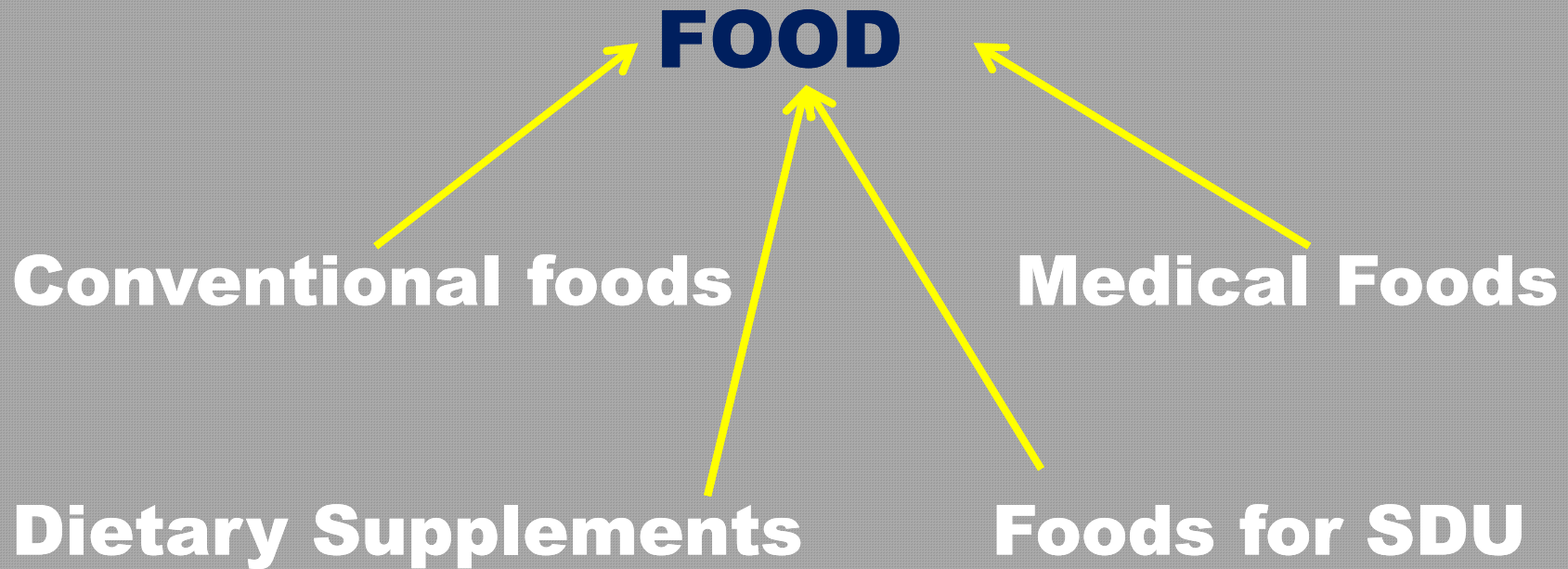
USDA



Strategies / Tactics

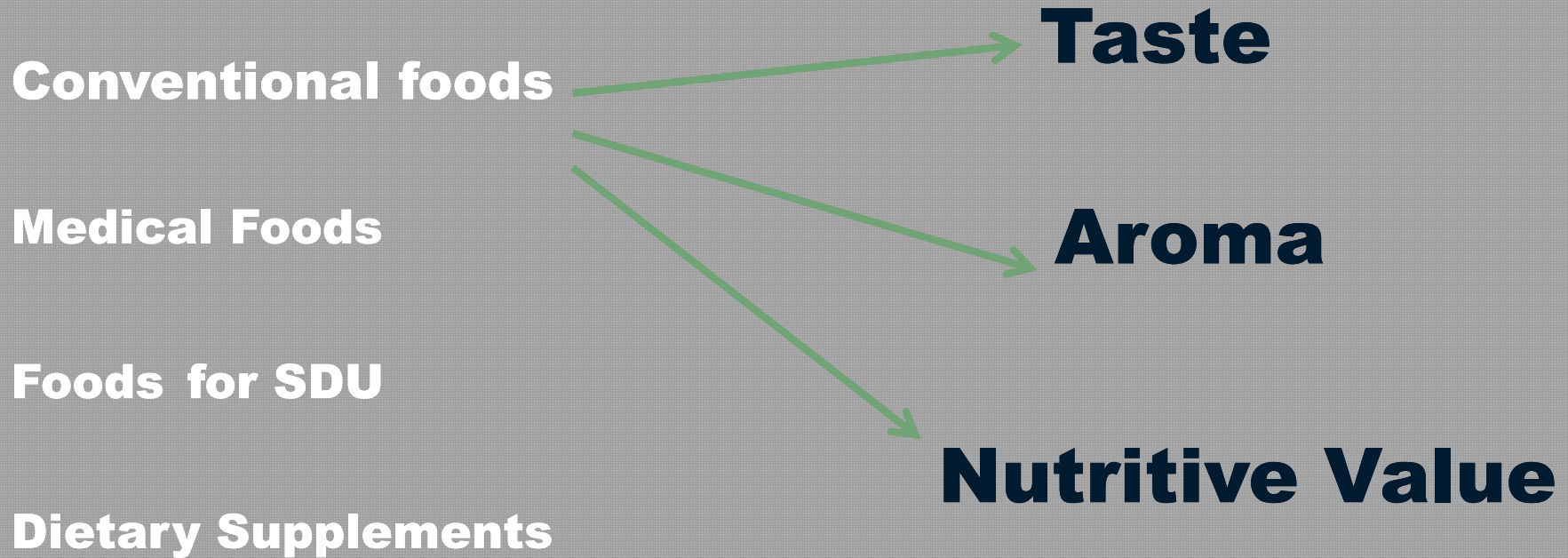
- **Focus on the market**
 - **Who and why?**
 - **Relationship to revenue?**
- **Develop a statement of what your product will do or what it will offer the consumer**
- **Consider Trade-offs and product categorization / classification**

What kinds of foods are there?



What kinds of foods are there?

FOOD: “An article used for food for man or other animals”





Foods: “Taste, Aroma or Nutritional Value”



Conventional Foods

No PMA

Additives

Claims

“Special” foods

Usually no PMA

Medical foods

Foods for special dietary uses

Dietary Supplements

No PMA

Additives and NDIs

Claim notification



Claims and Ingredients

Health claims

Nutrient content claims

Characterizing ingredients

Heart therapy.

100% Pomegranate Juice.
The Antioxidant Superpower:



A Tale of Two Labels

Nutrition Facts

Serving Size 2/3 cup (55g)
Servings Per Container About 8

Amount Per Serving

Calories 230 Calories from Fat 40

% Daily Value*

Total Fat 8g **12%**

Saturated Fat 1g **5%**

Trans Fat 0g

Cholesterol 0mg **0%**

Sodium 160mg **7%**

Total Carbohydrate 37g **12%**

Dietary Fiber 4g **16%**

Sugars 1g

Protein 3g

Vitamin A 10%

Vitamin C 8%

Calcium 20%

Iron 45%

* Percent Daily Values are based on a 2,000 calorie diet.
Your daily value may be higher or lower depending on
your calorie needs.

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Nutrition Facts

8 servings per container

Serving size 2/3 cup (55g)

Amount per 2/3 cup

Calories **230**

% DV*

12% **Total Fat** 8g

5% **Saturated Fat** 1g

Trans Fat 0g

0% **Cholesterol** 0mg

7% **Sodium** 160mg

12% **Total Carbs** 37g

14% **Dietary Fiber** 4g

Sugars 1g

Added Sugars 0g

Protein 3g

10% **Vitamin D** 2 mcg

20% **Calcium** 260 mg

45% **Iron** 8 mg

5% **Potassium** 235 mg

* Footnote on Daily Values (DV) and calories
reference to be inserted here.



Food Safety Responsibilities and Concerns

Brand Owner

Develops and owns the product

Sets and monitors the standards

Builds & maintains the brand

Drives sales and customer service

**Satisfies FDA / Food Safety
requirements**





Basic Safety-Related concepts for Manufacturing Contracts

Traceability

Ingredients (foreign supplier verification)

Finished product specifications

Quality Systems Audits

Records access

Immediate notice

Consequences

- **Recall**
- **Seizure / Injunction**
- **Disgorgement of Profits or Sales**
- **Fines or imprisonment**





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Jason Sapsin JD, MPH

Fox Rothschild LLP

jsapsin@foxrothschild.com