

# ADVERTISING HEALTH

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# Talking about Health...

## ■ FDA Health Claim

Statement about a relationship between a food, ingredient or dietary supplement and reduced risk of a disease or health-related condition.

## ■ Structure/Function Claim

Statement describing the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the body.

## ■ Qualified Health Claims

## ■ Nutrient Content Claims

## ■ General Well-being



# Obama “Let’s Move” initiative



- New rules from the White House and USDA prohibit advertisements for unhealthy foods on school campuses during the school day, including sugary drinks
- Beginning in September, calorie, fat, sugar and sodium limits now will have to be met on almost every food and beverage sold during the school day



# Implied Health Benefits



# A Tale of Two POMs

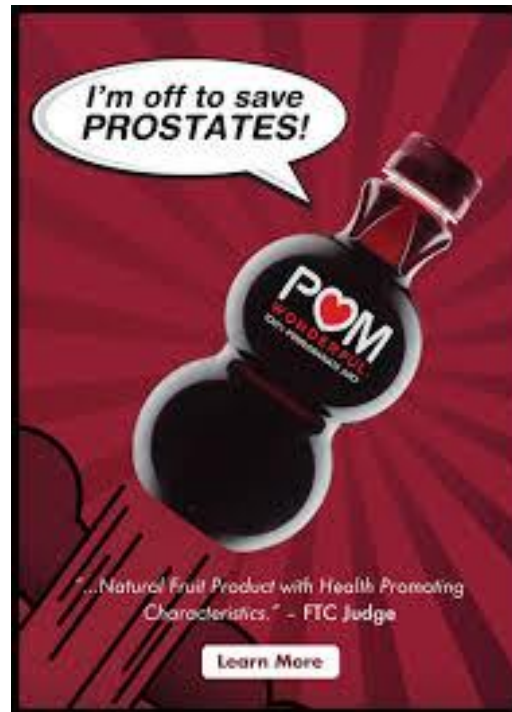


- In the Matter of POM Wonderful, Inc.

- POM Wonderful v. Coca- Cola



# In the Matter of POM Wonderful, LLC FTC No. 9344



The claims included treatment and/or reduction of risk of heart disease, prostate cancer, erectile dysfunction



# FTC Findings

## ■ Implied Claims:

- reasonable consumers would understand these statements as conveying the claim that consuming the products substantially reduced the likelihood that the consumer would contract the disease or condition.

## ■ Establishment Claims (i.e., clinically proven)

## ■ Specific health claims required RCTS

## ■ FTC distinguishes between disease claim and more general health benefit claims:

- “claims regarding general health benefits for heart, prostate, or erectile function are not the equivalent of claims to treat, prevent or reduce the risk of heart disease, prostate cancer, and erectile dysfunction”



# Competent and Reliable Scientific Evidence

■ tests, analysis, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.”

## ■ Pfizer Factors

- Type of product
- Type of claim
- Benefits of the claim if it is true
- Consequences if the claim is false
- Ease and cost of developing substantiation
- Level of substantiation experts in the field would agree is reasonable





# POM Wonderful v. Coca-Cola Co.

Question of “whether the court of appeals erred in holding that a private party cannot bring a Lanham Act claim challenging a product label regulated under the Food, Drug and Cosmetic Act.”



Pomegranate Blueberry  
Flavored Blend of 5 Juices



# Today's "hot button" areas

- "All Natural"
- Immune system benefits
- Antioxidants / "Superfood" ingredients
- Disease: heart health, diabetes, cancer
- Weight loss



# NAD and Health-related Claims



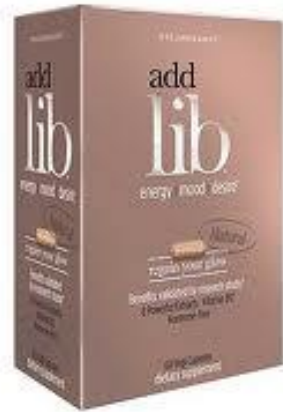
**“Smooth dark chocolate covered real fruit juice pieces.”**

**“Natural Source of Flavanol Antioxidants”**

**The Hershey Company , Case #5688 (2014)**



# NAD and Health-related Claims

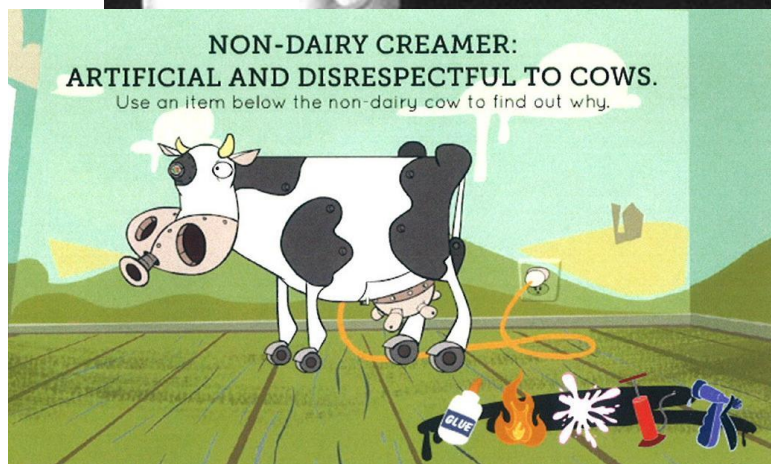
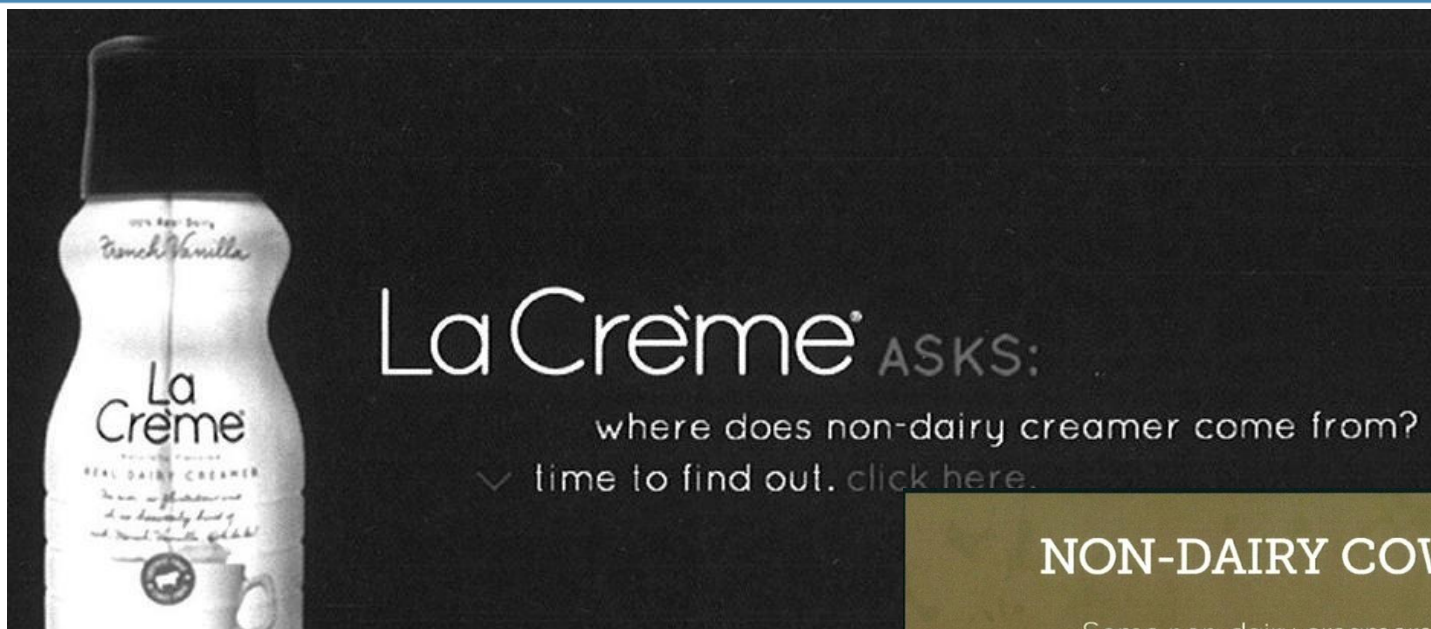


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**“A unique botanical blend that naturally restores energy, a healthy mood, and desire.”**



# Disparagement and Comparative “health” claims



close X

## NON-DAIRY COW TIP:

Some non-dairy creamers contain ingredients also used in paint.



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LaLa USA (La Crème), NAD Case # 5359 (2011)



# Health Benefits and Personal Care Products

2012 FDA Warning Letters affirming that certain claims cross the line between cosmetics and OTC Drugs:

- Hair removal
- Blemish removal
- Anti-Aging

Statements that products “counteract,” “retard,” or “control” = Drug claims

Statements that a product can “rejuvenate,” “repair,” or “restructure” would be viewed as drug claims, depending on context



# Health Benefits and Personal Care Products



“the first doctor recommended antifungal nail polish with an FDA approved fungicide to treat and prevent fingernail and toenail fungus.”

Alde Associates, Report #5565 (2013)



# What else you need to know about Advertising Health – Privacy and HIPAA

- . **The Health Insurance Portability and Accountability Act of 1996**
- . **HIPAA Privacy** – Protection for the privacy of Protected Health Information (PHI)
- . **HIPAA Security** – Protection for the security of electronic Protected Health Information (e-PHI)
- . **Covered Entity** - health care providers, health plans, and companies that process health claims, bill for health services.
- . **(September 2013) Business Associates** - provides “consulting, data aggregation, management [or] administrative...services” to or for a Covered Entity....”





Thank you!

Questions?

