



U.S. Food and Drug Administration  
Protecting and Promoting Public Health

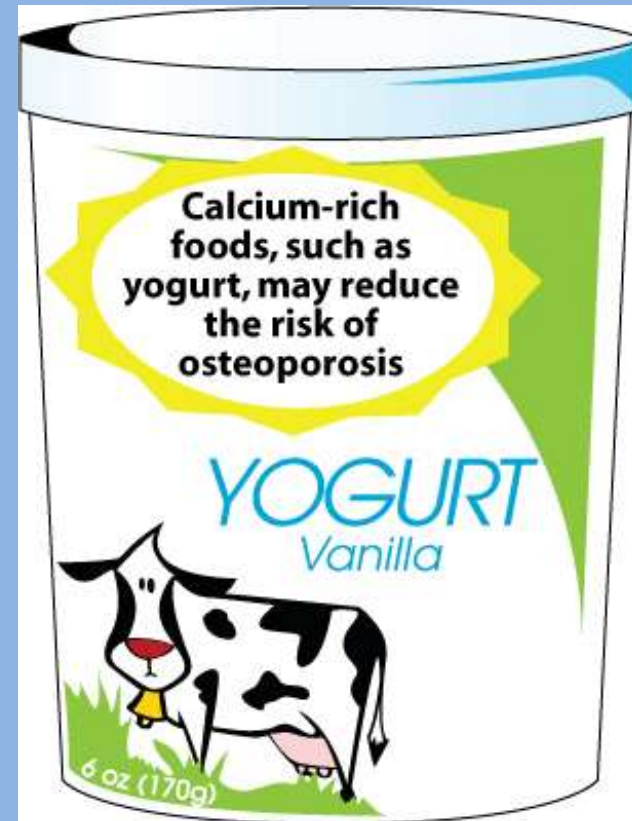
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# Nutrition labeling: regulatory tools for promoting public health

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# The Nutrition Facts Label and Health Claims





**Nutrition Facts**  
Serving Size 1 Cup (28g)  
Serving Per Container about 3

# Nutrition Labeling and Education Act of 1990\*

- Requires nutrition labeling on most food packages and nutrients
- Nutrients presented in context of a daily diet
- Help consumers maintain healthy dietary practices
- Encourage innovations in food products

\*Amended the 1938 Federal Food, Drug and Cosmetic Act (FFDCA)

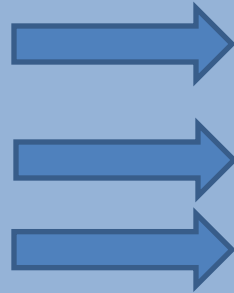


# Nutrition Facts Label and NCD risk

- Well-established scientific evidence linking nutrient & chronic disease risk, a health-related condition, or physiological endpoint
- Nutrients for which the RDA\* or AI\* are based on chronic disease risk, a health-related condition, or physiological endpoint

\*RDA= Recommended Dietary Allowance; AI = Adequate Intake

# Examples of nutrients and NCD risk



Nutrition Facts			
Serving Size 1/2 cup (about 82g)			
Servings Per Container 8			
Amount Per Serving			
Calories 200		Calories from Fat 130	
		% Daily Value*	
Total Fat	14g		22%
Saturated Fat	9g		45%
Trans Fat	0g		
Cholesterol	55mg		18%
Sodium	40mg		2%
Total Carbohydrate	17g		6%
Dietary Fiber	1g		4%
Sugars	14g		
Protein	3g		
Vitamin A 10% • Vitamin C 0%			
Calcium 10% • Iron 6%			
*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:			
	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Saturated Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300 mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g
Calories per gram:			
Fat 9 • Carbohydrate 4 • Protein 4			



# Elements of a health claim

- Causal relationship between a *substance* and a *disease or health-related condition for the general U.S. population or subpopulation* (e.g., women, elderly)
- Ability to reduce the risk of disease



# Selected Health Claims

## AUTHORIZED

- Calcium, Vitamin D and osteoporosis
- Dietary saturated fat and cholesterol and heart disease
- Fruits, vegetables and grain products (soluble fiber) and heart disease

## QUALIFIED

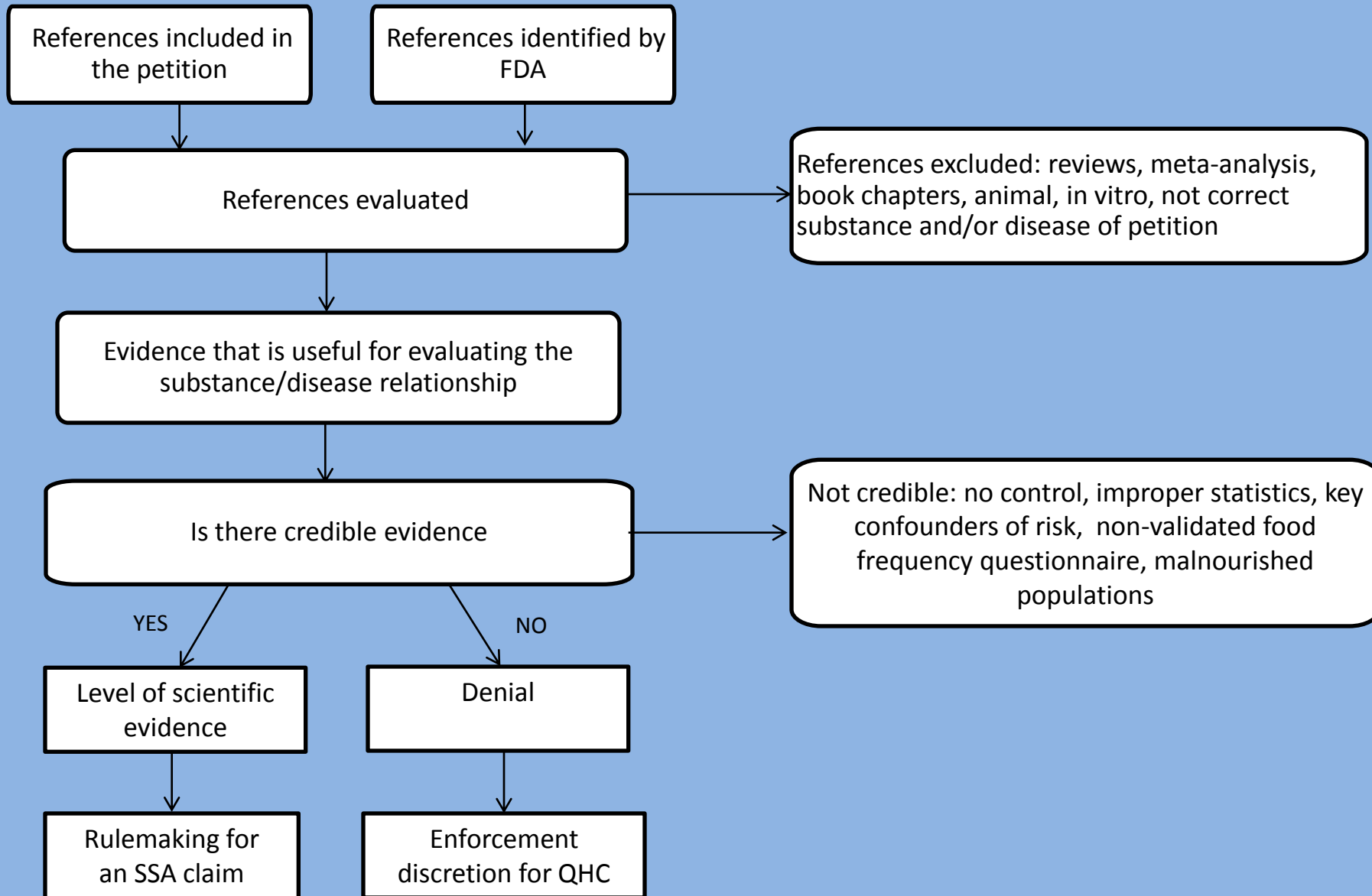
- Omega 3 fatty acids (EPA/DHA) and heart disease
- Walnuts and heart disease
- Tomato/lycopene and prostate cancer



FDA's evidence based review system for the scientific review of health claims

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm>

# Evidence-based review of health claims







# Some NCD risks considered in FDA regs

Nutrition Facts Label	NCD risk considered
Sat fat, trans fat, cholesterol	Coronary heart disease
Sodium	High blood pressure
Dietary fiber	Coronary heart disease
Health Claims	NCD risk considered
Soluble fiber	Coronary heart disease
Calcium, Vitamin D	Osteoporosis
Potassium	High blood pressure and stroke



# Summary

- NLEA authorized FDA to implement mandatory food labeling
- The Nutrition Facts label informs consumers about nutrients with roles in NDC risk (e.g., heart disease, high blood pressure)
- Health claims are FDA approved statements that communicate information about nutrients and reduced risk for disease (e.g., heart disease)

# Labeling helps us make healthy choices



# FDA's Center for Tobacco Products: The Regulation of Tobacco Products to Reduce the Burden of NCDs

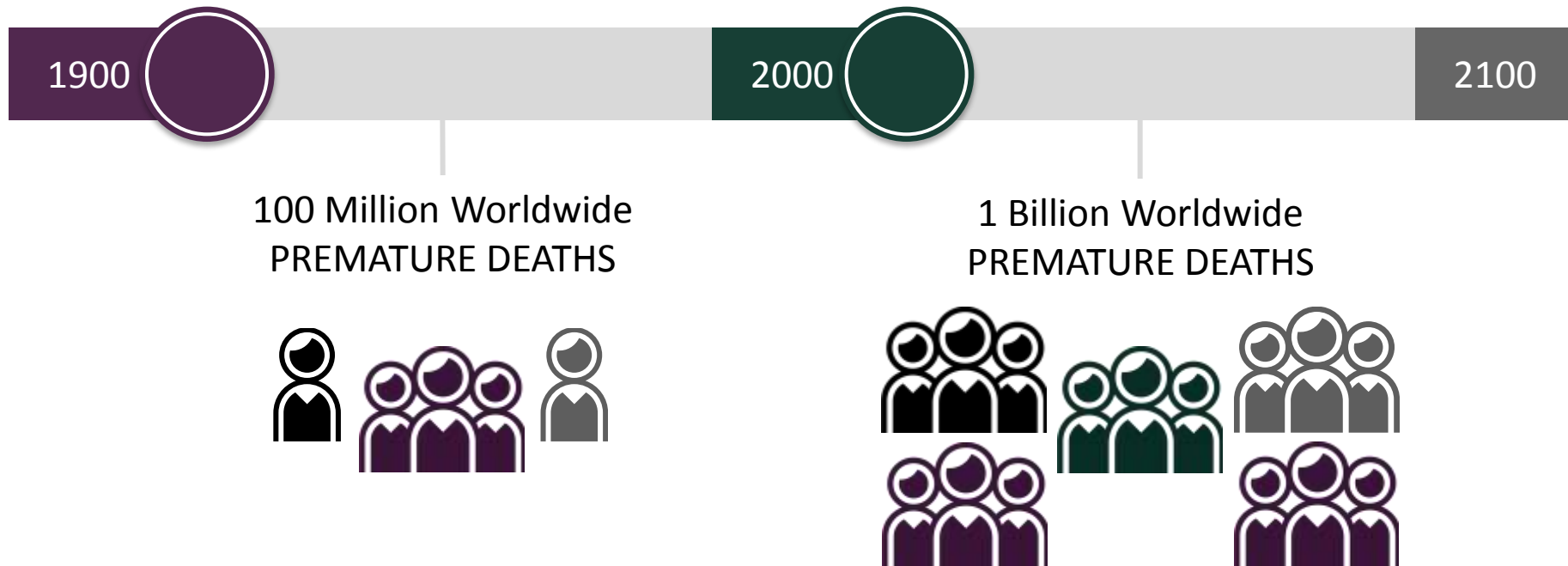


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# FIGHTING AN UPHILL BATTLE AGAINST DISEASE AND DEATH





# IMPLEMENTING THE TOBACCO CONTROL ACT

CTP has authority to regulate tobacco products intended for human consumption to reduce harm across the population

- Regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own, and smokeless
- Assert jurisdiction over other products that meet the definition of a tobacco product, including e-cigarettes, cigars, and hookah



# FULFILLING PROVISIONS OF THE LAW

CTP specific authorities include:

- Require tobacco manufacturers to register with the FDA
- Require listing of products and ingredients
- Require reporting levels of harmful constituents (HPHC)
- Establish tobacco product standards
- Establish limits on sale and distribution of tobacco products
- Require pre-market review for new and modified risk tobacco products (MRTPs) to protect the public health
- Require health warnings on labels and in advertising
- Establish limits on advertising and promotion of products

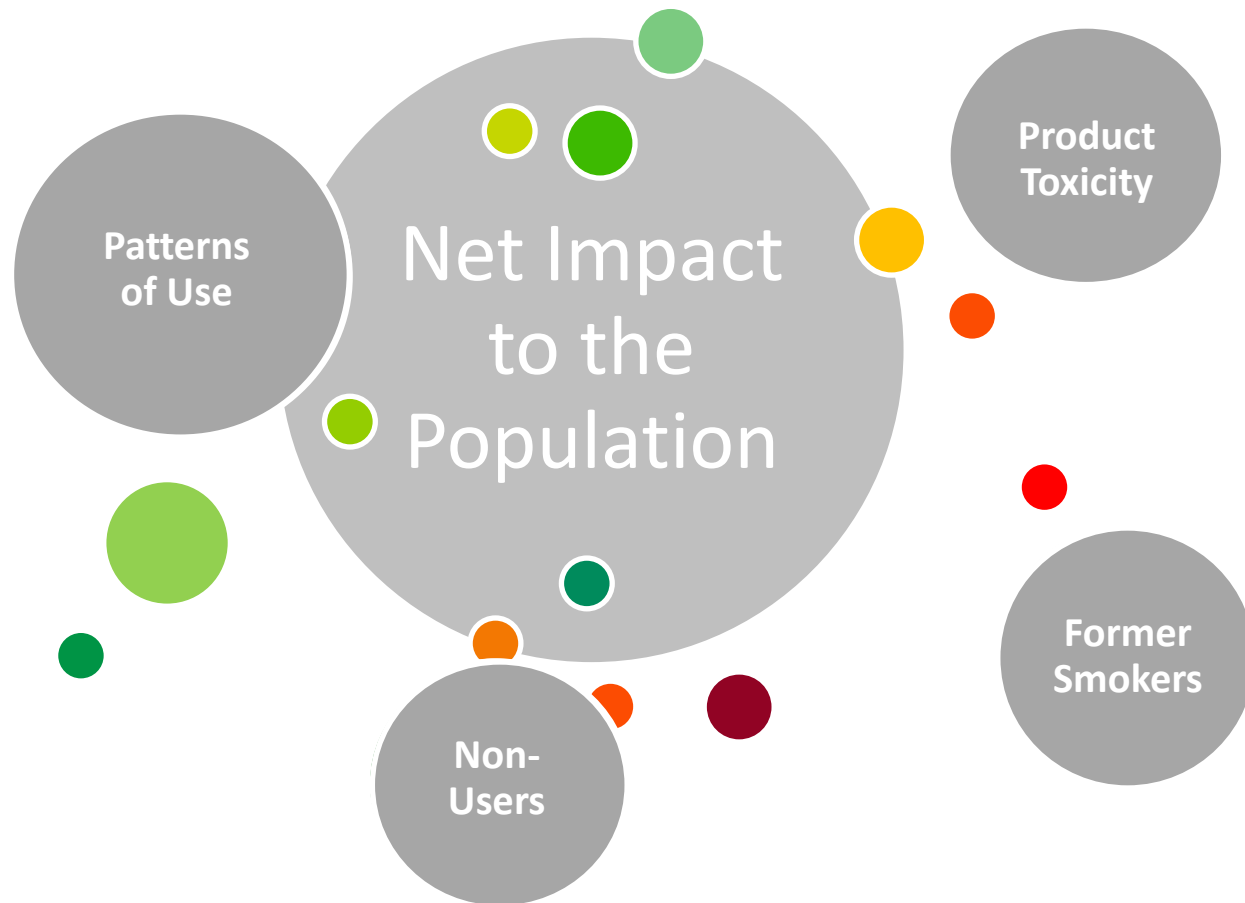


# ACTING TO IMPROVE PUBLIC HEALTH

- Prevent youth tobacco initiation
- Encourage adults who use tobacco to quit
- Reduce product harms and addictiveness



# ASSESSING OVERALL IMPACT TO PUBLIC HEALTH



# PURSuing STRATEGIC PRIORITIES

- Product Standards
- Comprehensive FDA Nicotine Regulatory Policy
- Pre & Post-Market Controls: Regulations & Product Reviews
- Compliance and Enforcement
- Public Education



# IMPLEMENTING ONE OF THE LAW'S MOST POWERFUL TOOLS

- Advancing a product standard strategy that yields strong standards to improve public health and that can withstand legal challenge
- Exploring potential standards for:
  - Addictiveness
  - Toxicity
  - Appeal



# LOOKING AT NICOTINE DIFFERENTLY

- Establish an integrated, FDA-wide policy on nicotine-containing products that is public-health based
- Implications for tobacco, drug, and device regulatory policy



# PROTECTING CONSUMERS



As the regulatory gatekeeper, CTP now stands between tobacco products and consumers

# ENFORCING THE LAW

- Inspect, investigate, monitor and review activities
- Initiate appropriate enforcement actions that are supported by evidence
  - Develop and document sufficient evidence to support enforcement actions for violations of the law
  - Expand state inspection program to remaining states and territories
  - Plan for implementation of compliance activities for newly deemed products
  - Implement compliance inspection, education, and enforcement activities on tribal lands



# EDUCATING AT RISK AUDIENCES ON THE DANGERS



10  
Million



**General “At Risk” Market**  
**Multicultural**  
**Rural**  
**American Indian/  
Alaska Native**  
**LGBT**

**Prevention**



**Investing in  
our Future**

