



# Evaluating the Science of Health Claims on Foods

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## Main Questions

- How does the U.S. Food and Drug Administration (FDA) regulate food claims related to nutrition?
- How are claims substantiated and communicated?

FDA derives legal authority for regulation of food labeling from statutes enacted by the Federal government.

■ The Primary Statutes for FDA's Legal Authority and Procedures

- 
- Federal Food, Drug and Cosmetic Act (FFDCA), as amended
- Fair Packaging and Labeling Act
  - Public Health Service Act
  - Administrative Procedures Act

## How does FDA use its legal authority?

### Development of policy, including regulations and guidance documents

- Final regulations are published in the Code of Federal Regulations (CFR)
- Enforcement and compliance activities
- Research to support the mission
- Outreach and education



# Goals of the Nutrition Labeling & Education Act\*

Mandatory Information

| Nutrition Facts   |                            |
|---|----------------------------|
| Serving Size 1 cup (247g)   |                            |
| Servings Per Container about 2  |                            |
| Amount Per Serving  |                            |
| Calories 110  | Calories from Fat 15       |
| % Daily Value*  |                            |
| Total Fat 2g  | 3%                         |
| Saturated Fat 0.5g  | 3%                         |
| Trans Fat 0g  |                            |
| Cholesterol 10mg  | 3%                         |
| Sodium 480mg  | 20%                        |
| Total Carbohydrate 18g  | 6%                         |
| Dietary Fiber 4g  | 16%                        |
| Sugars 3g   |                            |
| Protein 7g  |                            |
| Vitamin A   | 20%                        |
| Vitamin C   | 0%                         |
| Calcium   | 4%                         |
| Iron  | 8%                         |
| * Percent Daily Values are based on a diet of other people's secrets.     |                            |
| Your Daily Values 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                    |
| Calories per gram:  |                            |
| Fat 9   | Carbohydrate 4 • Protein 4 |

Voluntary Information



Authorization of Health Claims  
and  
Nutrient Content Claims

\*NLEA amended the FFDCA in 1990.

# Types of Claims Related to Health and Nutrition Allowed on Foods or Dietary Supplements

## ■ Dietary Guidance

- Message that refers to a general category of foods and health

## ■ Nutrition Support Statements on dietary supplements

- Statements of well-being
- Structure Function Claims
- Classical nutrient deficiencies (+prevalence)

# Types of Claims Related to Health and Nutrition Allowed on Foods and Dietary Supplements

## ■ Nutrient Content Claims

- Reference to the nutrient level in a product

## ■ Health Claims

- Characterizes a relationship between a food or food component and reducing risk of disease or health-related condition

Note: Codex definition of health claim differs in that it includes nutrient function claims, other function claims, and reduction of risk claims.

## Claims Used on Foods and Dietary Supplements

- Does not require a premarket action by the agency
  - Dietary Guidance Statements
  - Nutrition Support Statements
- Requires premarket actions by the agency
  - Nutrient Content Claims
  - Health Claims





## Expressed Nutrient Content Claims

- Describe the level of a nutrient or dietary substance
  - *Free; high; low; contains*
  - *Good or excellent source*
- Compare the level of nutrient or dietary substance to another food
  - *More; reduced; light (lite)*



## Examples of Expressed Claims

| Type of claim | Criteria  | Synonyms  | Comments   |
|---------------|---|---|--|
| "Good" source | At least 10% of RDI or DRV (i.e. DV)                          | provides, contains etc.                                 | Cannot use without an established DV.              |
| "High" source | At least 20% of the RDI or DRV (i.e. DV)                      | excellent, etc.   |  |
| Free or low   | Grams or mg per RACC or labeled serving based on nutrient     | Zero, without, insignificant; little, small amount etc. | See regulations for additional terms and criteria. |
| Reduced       | At least 25% less per RACC than an appropriate reference food | Less, fewer etc.  |  |

Terms: RDI=Reference Daily Intake, DRV=Daily Reference Value; DV=Daily Value  
RACC=Reference Amount Customarily Consumed

## Implied Nutrient Content Claims

- Suggests that a nutrient is present or absent in a certain amount
  - *e.g. "contains no oil"; "only"*
- Equivalence claims
  - *e.g. "as much vitamin C as an 8 oz of orange juice"*
- Claims that a food may be useful in maintaining healthful dietary practices
  - *e.g. Healthy*

## Criteria for Use of “Healthy”

|                             |   |
|-----------------------------|---|
|                             | <b>Individual Food</b> (RACC* is > 30 g)  |
| <b>Total Fat</b>            | 3 g or less/RACC (low)  |
| <b>Saturated Fat</b>        | 1 g or less/RACC & 15% or less calories (low)   |
| <b>Sodium</b>               | 480 mg or less/RACC & per labeled serving   |
| <b>Cholesterol</b>          | 60 mg or less/RACC & per labeled serving  |
| <b>Beneficial Nutrients</b> | At least 10% DV per RACC for one or more of vitamins A, C, iron, calcium, protein, or fiber |

\*RACC is Reference Amount Customarily Consumed

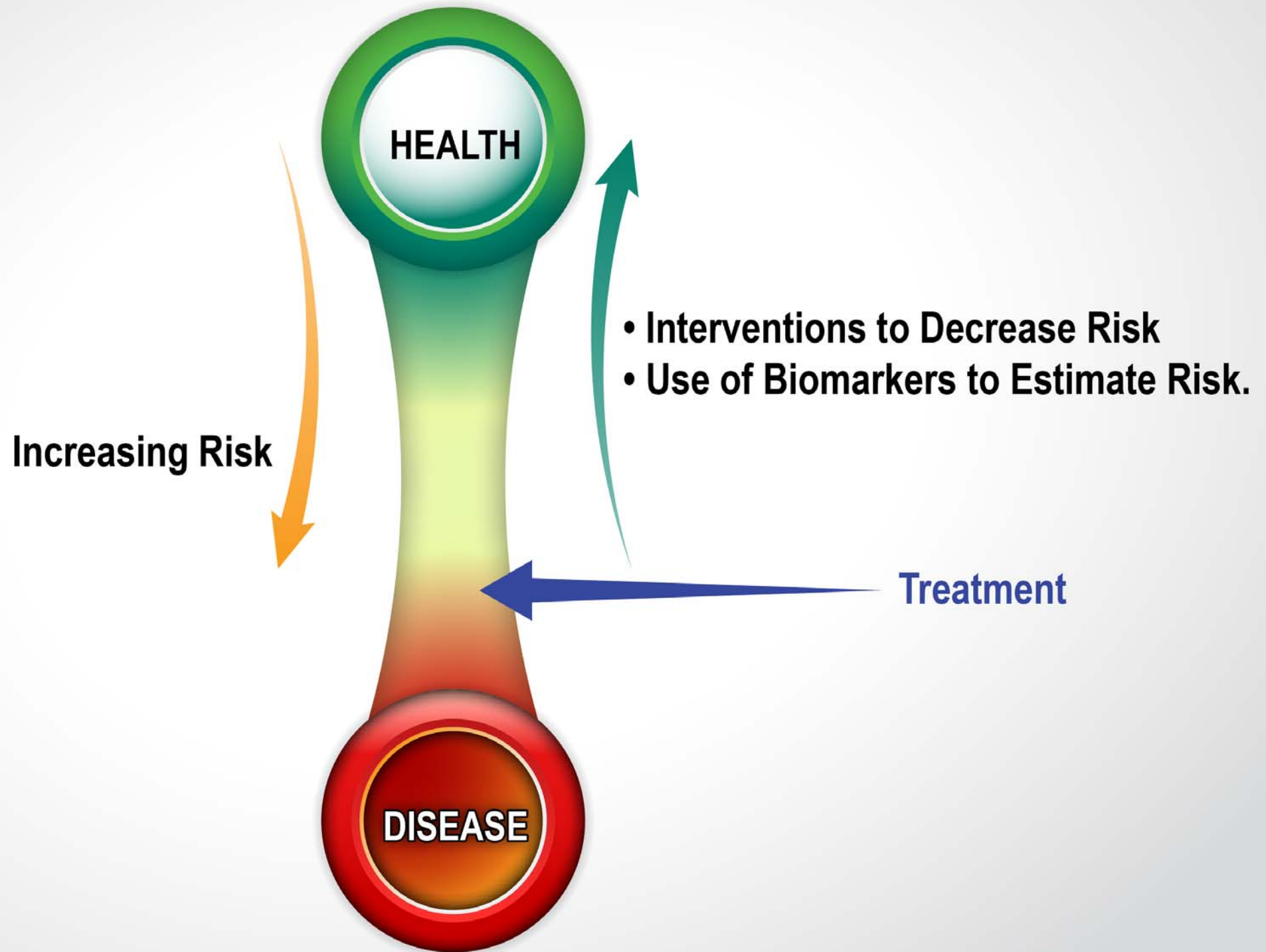


## Purpose of Health Claims

- To allow foods (including dietary supplements) to bear certain science-backed claims about reducing disease risk in their labeling without being regulated as drugs
- Risk reduction claims
  - Health claims are about reducing the risk of a disease or health-related condition, not treating, mitigating, preventing, or curing diseases.

*Whitaker v. Thompson*, 353 F.2d 947 (D.C. Cir. 2004)

# REDUCING RISK FOR DISEASE

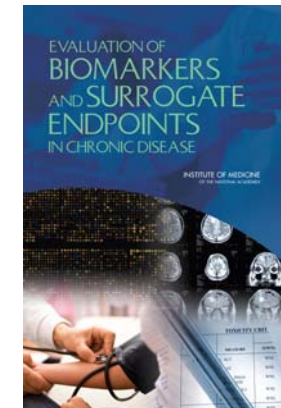


# Use of Biomarkers as Surrogate Endpoints

## ■ Acceptable biomarkers

- CHD: LDL-cholesterol or plasma cholesterol; blood pressure
- Diabetes: Blood sugar levels; insulin resistance
- Dementia: Mild cognitive impairment
- Colon/rectal cancer: Polyps
- Osteoporosis: Bone mineral density

## ■ Institute of Medicine project on biomarkers



# Elements of a Health Claim

## ■ Substance

- A specific food or component of food, whether in conventional food or dietary supplement form.

## ■ Disease or health-related condition

- “Damage to an organ, part, structure, or system of the body such that it does not function properly ... or a state of health leading to such dysfunctioning ... ”
  - Nutrient deficiency diseases (e.g., scurvy) are not included in this definition.



# CONTINUUM OF SCIENTIFIC EVIDENCE

## Scientific Consensus

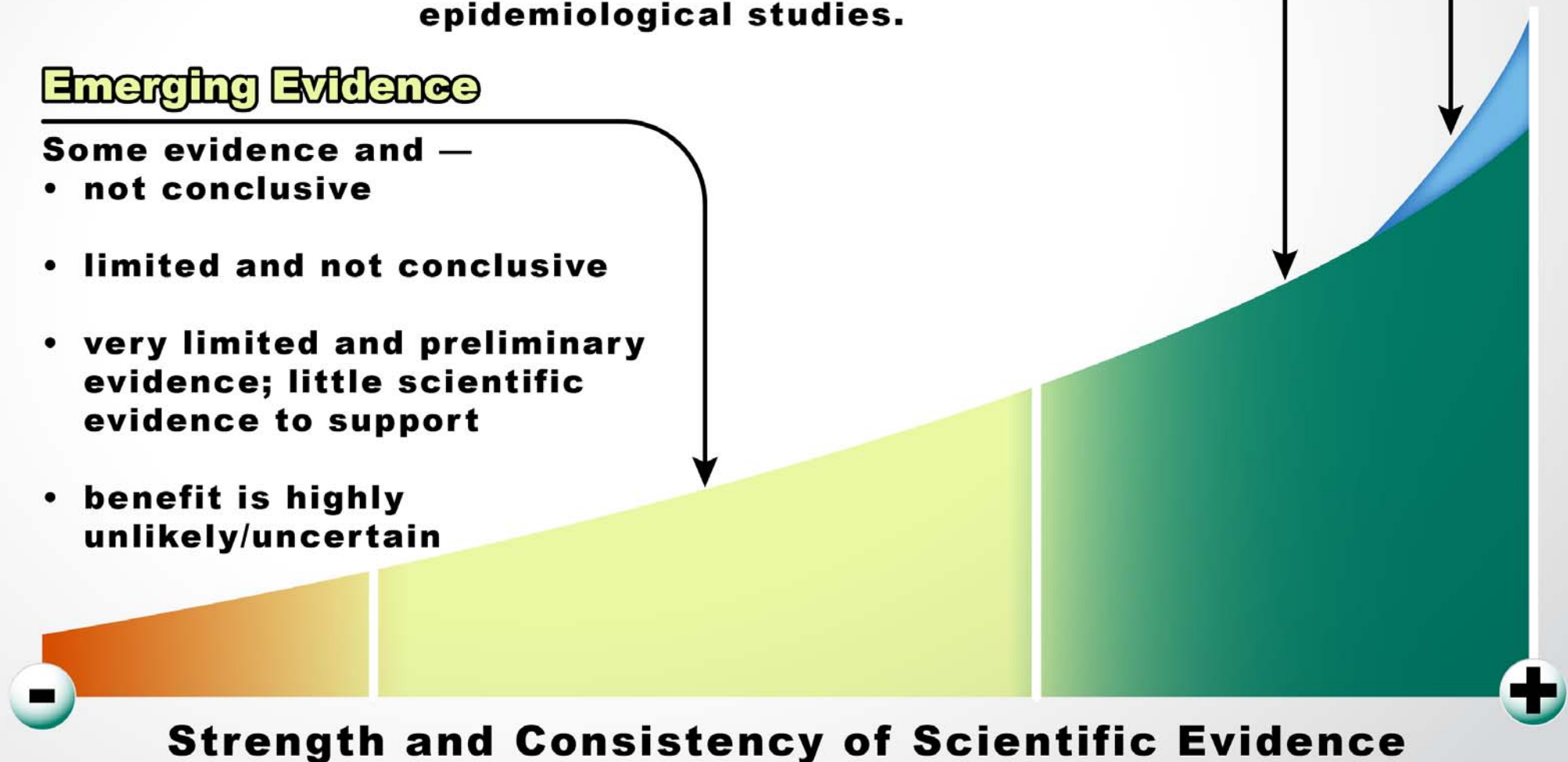
## Significant Scientific Agreement

Body of consistent, relevant evidence from well-designed clinical and/or epidemiological studies.

## Emerging Evidence

Some evidence and —

- not conclusive
- limited and not conclusive
- very limited and preliminary evidence; little scientific evidence to support
- benefit is highly unlikely/uncertain



# Health Claims in Food Labeling: Three Approaches

- **NLEA Health Claims**
  - Based on significant scientific agreement
  - Authorized through rulemaking
- **Qualified Health Claims**
  - Claims that characterize the quality and strength of the scientific evidence if the claim is **not** based on significant scientific agreement.
  - Use of enforcement discretion by the agency
- **Claims based on authoritative statements (FDAMA Notifications)**
  - Based on authoritative statements of a scientific body of the government or of the National Academy of Sciences

# How do structure/function claims, health claims, and qualified health claims differ?

## ■ Structure/Function claims

- Maintain function and structure (*e.g. calcium builds strong bones; compound y promotes weight loss*)
- Manufacturer is responsible for substantiating the claim



## Health claim

- Disease risk reduction (*e.g. Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors*)
- Authorized by FDA through rule-making



## Qualified health claim

- Indicates the strength of the science (may state benefit is *unlikely or uncertain*)
- Use of enforcement discretion

## Reviewing the Scientific Evidence for Health Claims

- Define substance/disease relationship
- Identify relevant studies
- Classify studies
- Rate studies for quality
- Rate for strength of body of evidence:  
Quantity, quality, consistency, relevance
- Report "rank"

All studies / publications  
included in the petition  
plus those identified  
by FDA

g Administration  
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Studies that  
are not useful for  
review or to draw  
scientific  
conclusions

## Process for Evaluation of Health Claims at FDA

Evidence that  
is useful for  
evaluating the  
substance/disease  
relationship

Is there credible  
evidence for a  
claim?

YES

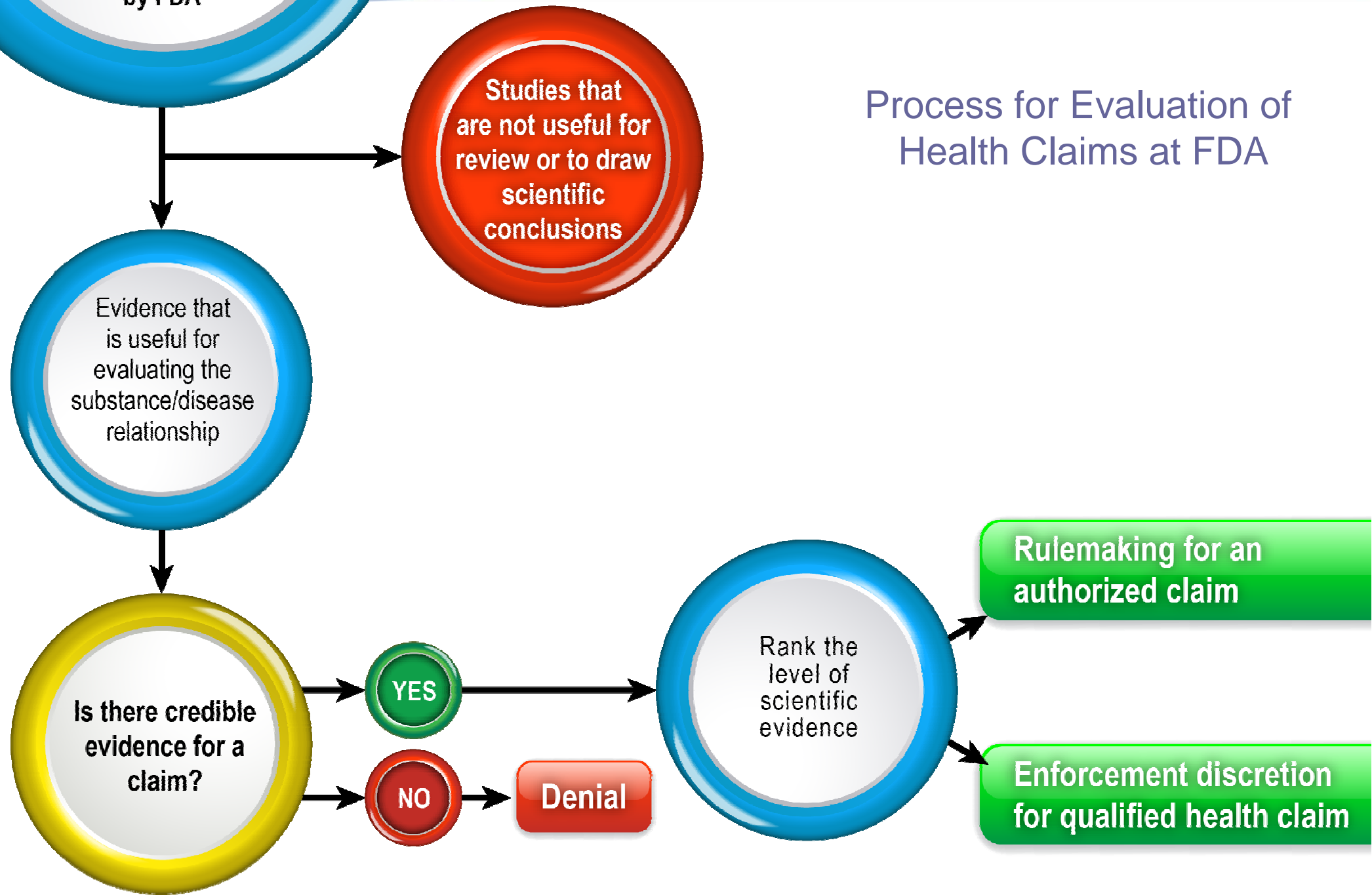
NO

Denial

Rank the  
level of  
scientific  
evidence

Rulemaking for an  
authorized claim

Enforcement discretion  
for qualified health claim




Studies that  
are not useful for  
review or to draw  
scientific  
conclusions

## Studies are reviewed for their usefulness in an Evidence-based review

- Studies not suitable for evidence-based review, e.g.
  - Review articles
  - Meta-analysis
  - Book Chapters
  - Abstracts
  - Animal studies
  - in vitro studies
  - Studies that do not pertain to the substance or disease
- Studies suitable for use in an evidence-based review
  - Human studies that evaluate the substance-disease relationship
  - Intervention studies
  - Observational studies






Studies that  
are not useful for  
review or to draw  
scientific  
conclusions

## Can scientific conclusion be drawn from the human studies?

- Were the subjects healthy or did they have the disease in the health claim?
- Was the disease of the claim measured as a “primary” endpoint?
- Was an appropriate control group included?
- Was the independent role of the substance in reducing risk measured?
- Were there relevant differences between control and treatment at baseline?
- What statistical analysis was used?

Continued . . .




Studies that  
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conclusions

Continued . . .

## Can scientific conclusion be drawn from the human studies?

- What type of biomarker was used?
- How long was the study conducted?
- Where were the studies conducted?
- What methods were used to estimate intake of the substance?
- In observational studies what type of information was collected?
- In observational studies was the substance a food or food component?





Studies that  
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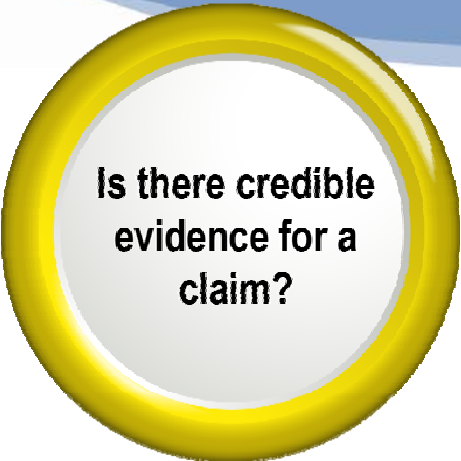
## Can scientific conclusion be drawn from the human studies?

- Examples of Fatal Flaws:
  - No control
  - Lacks relevant statistics
  - Key cofounders of risk not controlled
  - Non-validated biomarker as endpoint
  - Independent effect not evident from study design
  - Observational data without intake validation
  - Malnourished populations
  - Diseased population

Evidence that  
is useful for  
evaluating the  
substance/disease  
relationship

## Assessing the Methodological Quality of Studies (High, Medium, Low)

- Were studies randomized and blinded and was a placebo provided?
- Were inclusion/exclusion criteria and key information on study population provided?
- Was subject attrition assessed and reported?
- Was protocol compliance verified? How?
- Is baseline data analysis for all those initially enrolled or those who completed the study (intent to treat)?
- Was disease incidence or a surrogate endpoint measured?
- How was onset of disease measured?
- Was there adequate adjustment for confounders of disease risk?
- What type of dietary assessment method was used to estimate intake?



Is there credible  
evidence for a  
claim?

## The totality of scientific evidence is evaluated.

- Factors to be considered:
  - Number of studies and number of subjects per group
  - Methodological quality (high, medium, or low)
  - Outcome: Beneficial effect, no effect, adverse effect
  - Consistency
  - Relevance to the general U.S. population

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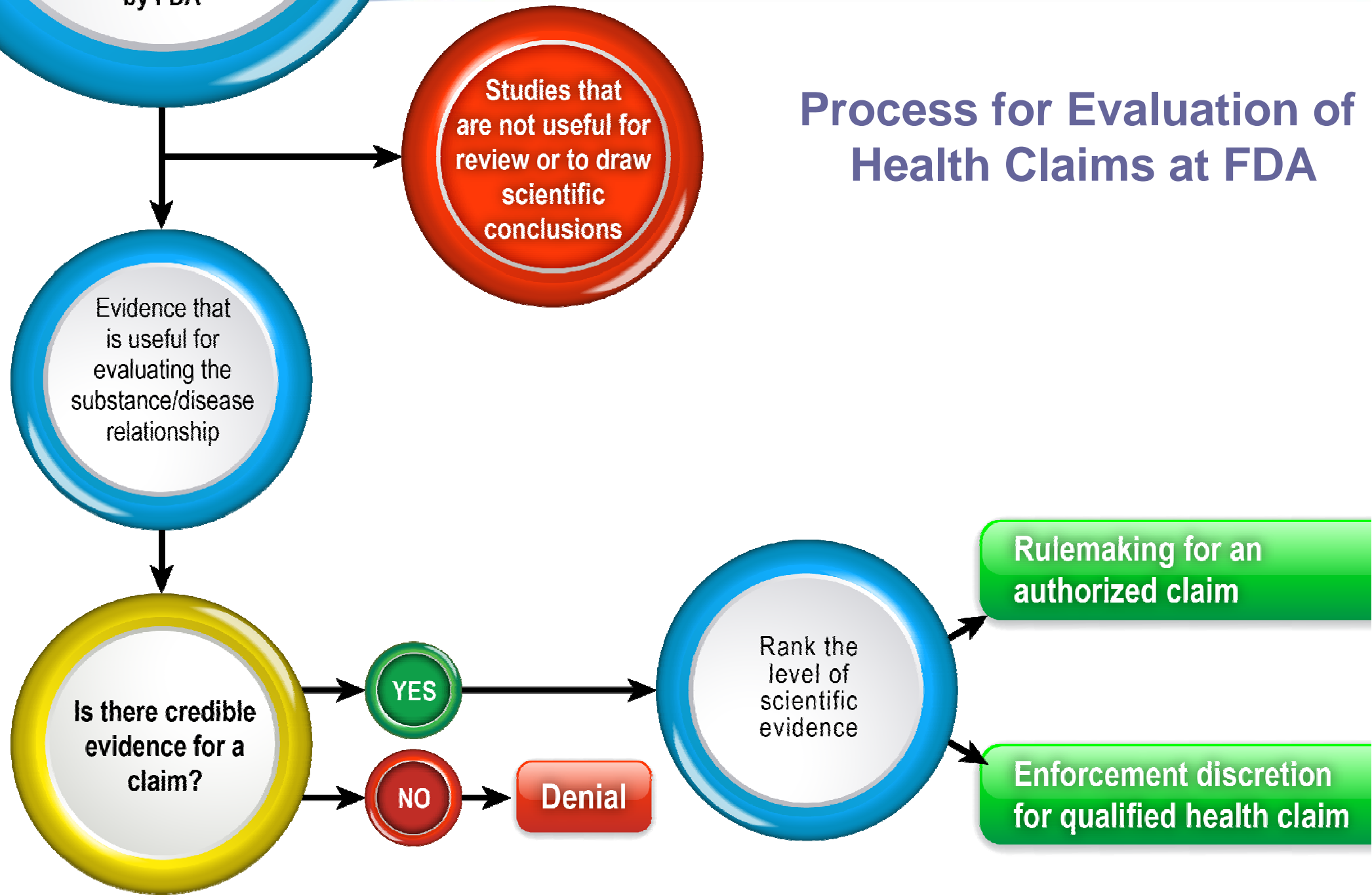
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Denial

Rank the  
level of  
scientific  
evidence

Rulemaking for an  
authorized claim

Enforcement discretion  
for qualified health claim



## Health claims and Qualified Health claims

### ■ Health claims (SSA)

- Calcium and osteoporosis
- Saturated fat and coronary heart disease (CHD)
- Soluble fiber and CHD
- Fiber containing fruits, vegetables, grains and cancer

### ■ Qualified Health claims

- Lycopene and cancer
  - Limited scientific evidence/highly uncertain
- Green tea and Cancer
  - “highly unlikely”
- Omega-3 Fatty acids and CHD
  - “supportive but not conclusive”



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U.S. Food and Drug Administration



Department of  
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CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

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CFSAN/Office of Nutrition, Labeling and Dietary Supplements  
January 2009

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## Guidance for Industry

# Evidence-Based Review System for the Scientific Evaluation of Health Claims



## Questions

*Additional Information:*

[www.FDA.gov](http://www.FDA.gov)

[http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/  
GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm](http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm)

Links to Claim language that can be used, including Letters of Enforcement Discretion for Qualified Health Claims at <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/default.htm>