http://www.uccalfresh.org/trainings/trainings

Nutrition Updates

September 4, 2018

Today's Expert Presenter

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UCDAVIS
DEPARTMENT of NUTRITION

UNIVERSITY OF CALIFORNIA
calfresh Nutrition Education

Today's Topic – Dietary Supplements

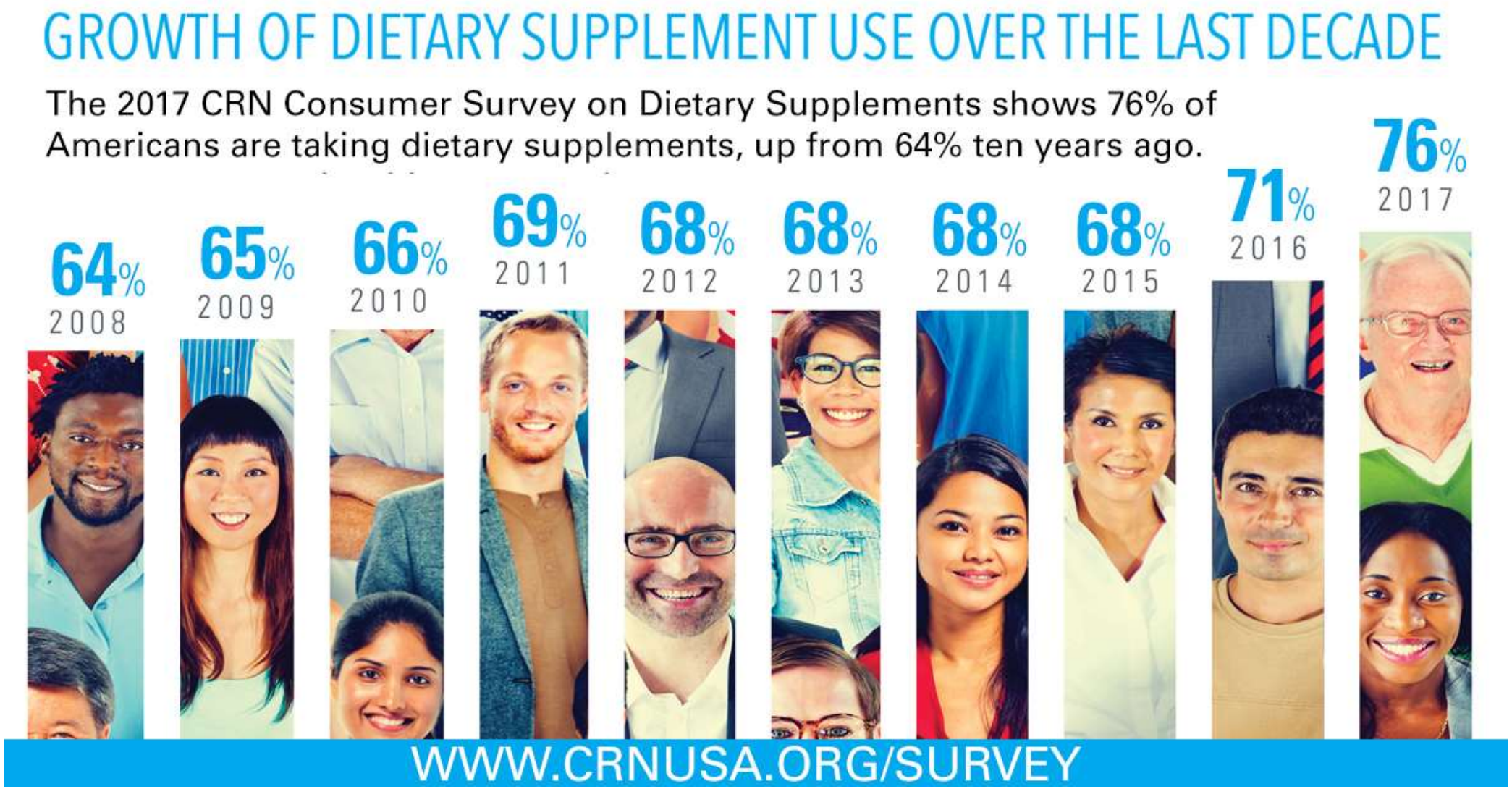
- Who is taking supplements?
- What supplements are they taking? And why?
- **Scientific Concept**—DRIs and More!
- How are dietary supplements regulated?
- What is defined as a supplement?
- When might a dietary supplement help?
- When can supplement use be dangerous?
- How can I handle questions about supplements in classes?

Poll

Which of these supplements have your class participants brought up or asked questions about? Mark all that apply.

- Protein or other muscle-building supplements
- Weight-loss supplements
- Probiotic supplements
- Fish oil or omega-3 fatty acid supplements
- Other supplement(s)
- None – no questions or discussion about supplements

Who is taking supplements?



A BOOST IN OVERALL USE

Increases in supplement use can be seen among all ages, with those 55+ increasing the most, from 74% to 80% since 2016.

74%
of U.S. adults
18–34

UP FROM 70% IN 2016

75%
of U.S. adults
35–54

UP FROM 70% IN 2016

80%
of U.S. adults
55+

UP FROM 74% IN 2016

WWW.CRNUSA.ORG/SURVEY

Even kids are taking supplements!

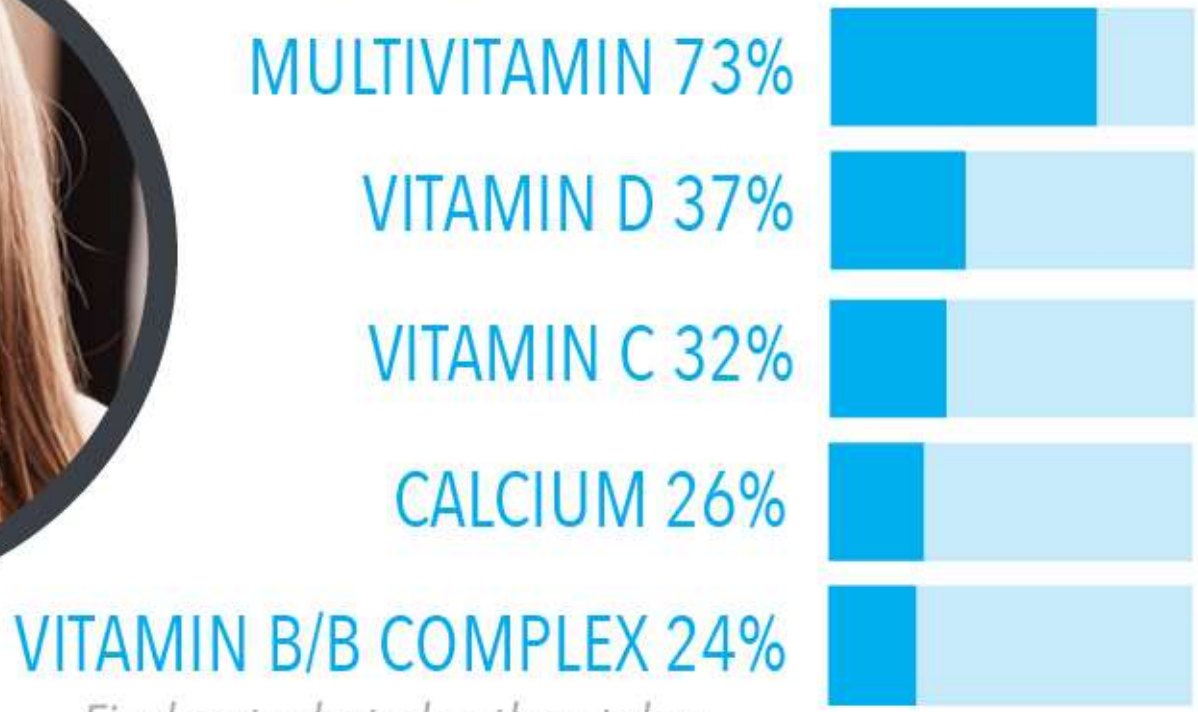
- According to a recent study, **approximately 1/3 of youth <19** report taking supplements including omega-3 fatty acids, multivitamins, and melatonin

https://jamanetwork.com/journals/jamapediatrics/article-abstract/2685282

WHAT DO DIETARY SUPPLEMENT USERS TAKE?

98% of supplement users take vitamins and minerals.

THE BREAK DOWN:



Find out what else they take:

WWW.CRNUSA.ORG/SURVEY

Specialty 49%

- OMEGA-3/FATTY ACIDS 21%
- PROBIOTICS 16%
- FIBER 14%
- MELATONIN 10%
- GLUCOSAMINE/CHONDROITIN 9%

Sports Nutrition 29%

- PROTEIN (POWDERS, DRINKS, BARS) 19%
- ENERGY DRINKS AND/OR GELS 12%
- HYDRATION DRINKS OR GELS 8%
- CREATINE 6%
- AMINO ACIDS 6%
- RECOVERY DRINKS AND/OR POWDERS 5%

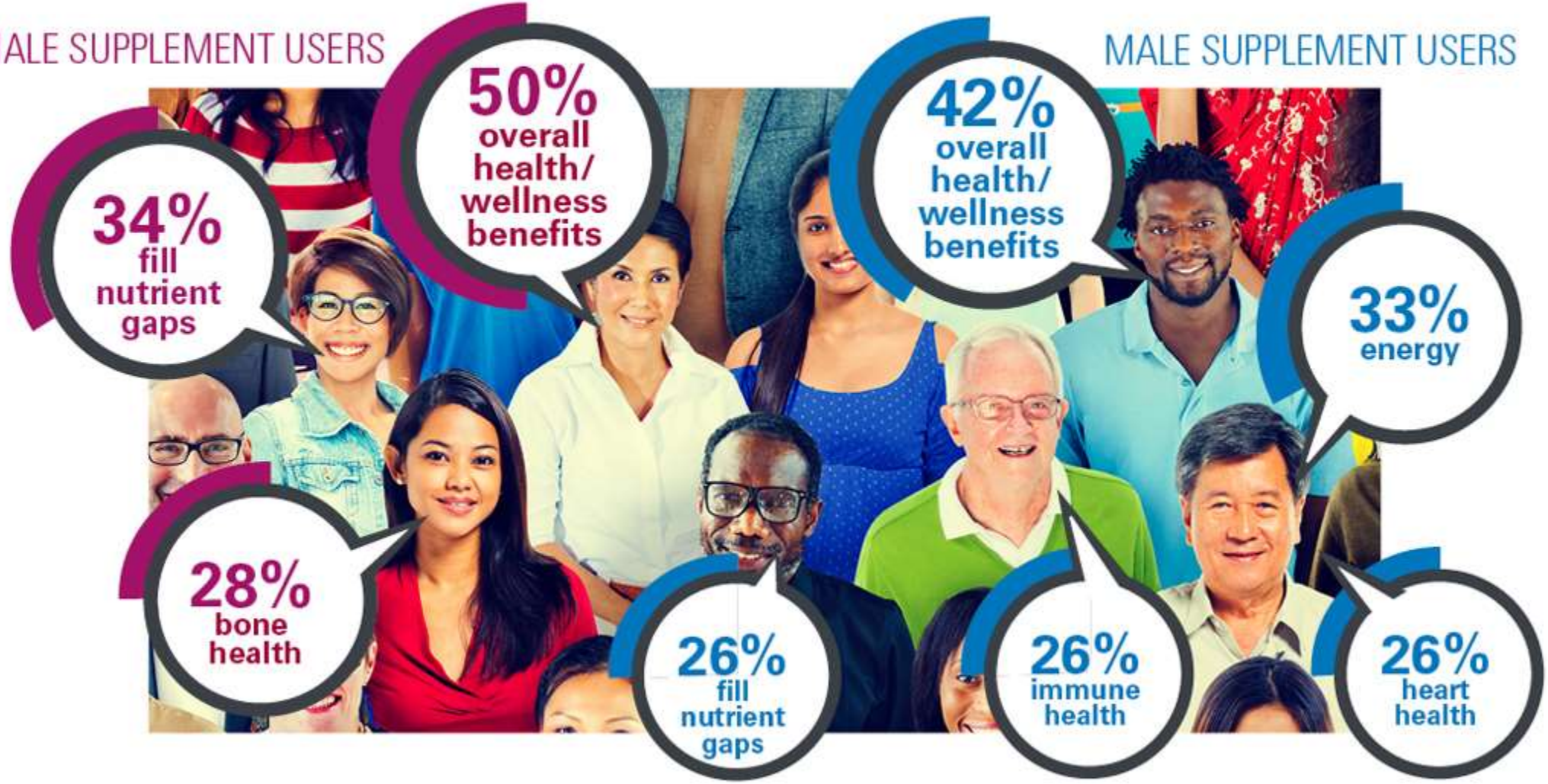
Herbals/Botanicals 39%

- GREEN TEA 14%
- CRANBERRY 9%
- TURMERIC 9%
- GARLIC 8%
- GINSENG 8%
- GINKGO BILOBA 6%
- MILK THISTLE 5%
- ECHINACEA 5%

Weight Management 19%

- PROTEIN (POWDERS, DRINKS, BARS) 10%
- GARCINIA CAMBOGIA 5%
- GREEN COFFEE 4%
- MEDIUM CHAIN TRIGLYCERIDE OIL 2%
- WHITE KIDNEY BEAN 2%
- BITTER ORANGE (SYNEPHRINE) 2%

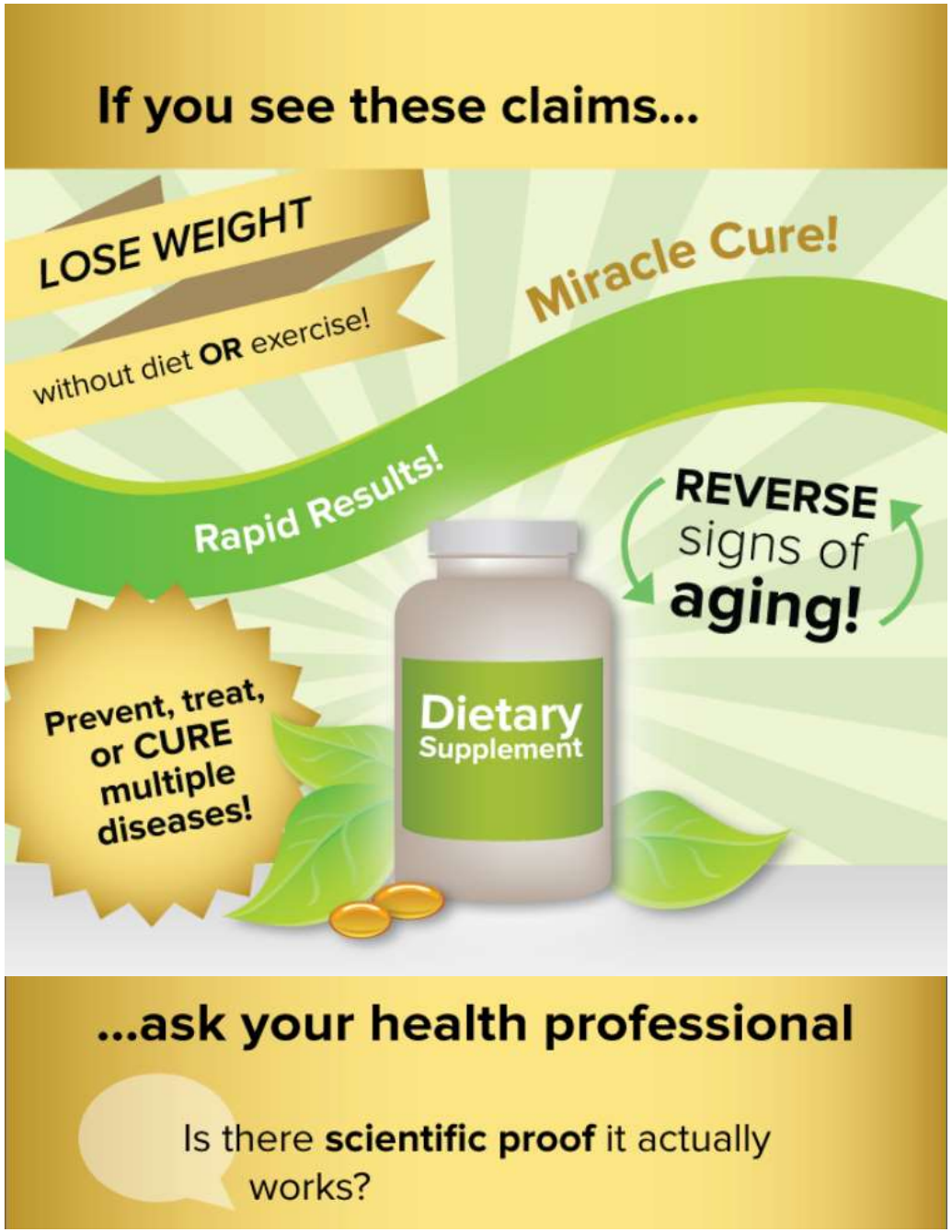
TOP REASONS FOR TAKING SUPPLEMENTS: WOMEN VS. MEN



WWW.CRNUSA.ORG/SURVEY

News vs Science

- Rapid fire of nutrition "breaking news"



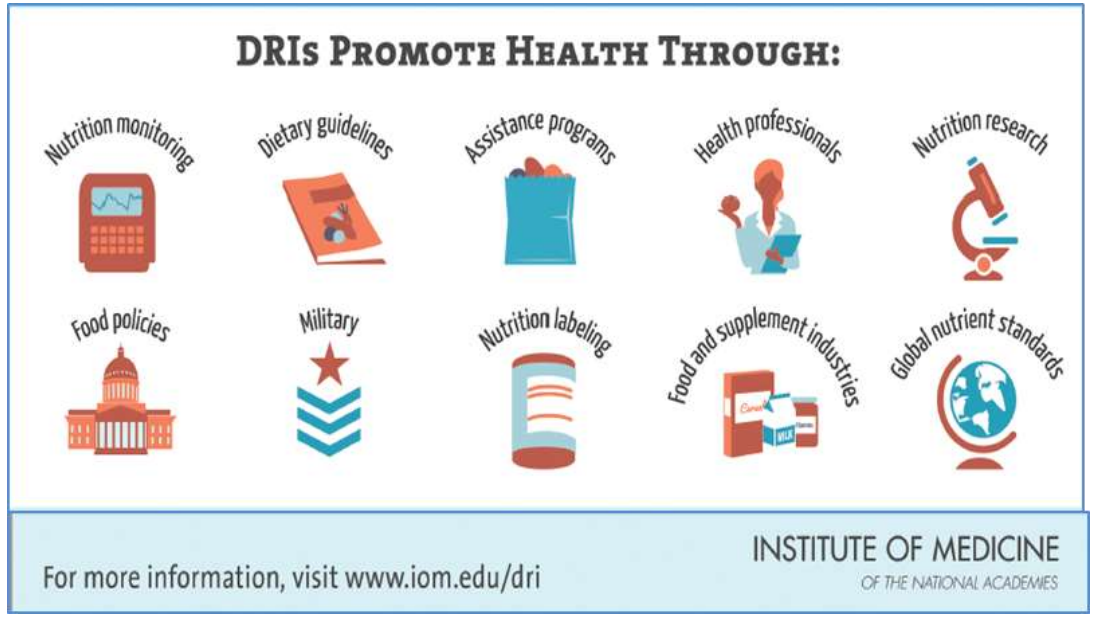
https://www.consumer.ftc.gov/articles/0538-dietary-supplement-ads-infographic

Recommendations and Standards for Human Nutrition

- DRI: Dietary Reference Intakes
  - EAR, RDA, AI, UL
  - AMDR (Acceptable Macronutrient Distribution Range)
  - EER (Estimated Energy Requirement)
- Food Labels: DV – Daily Values
  - RDI and DRV

Dietary Reference Intakes (DRI)

- Dietary Reference Intakes (DRI)
  - What are they?
  - What are they used for?
- Methods used to develop DRIs

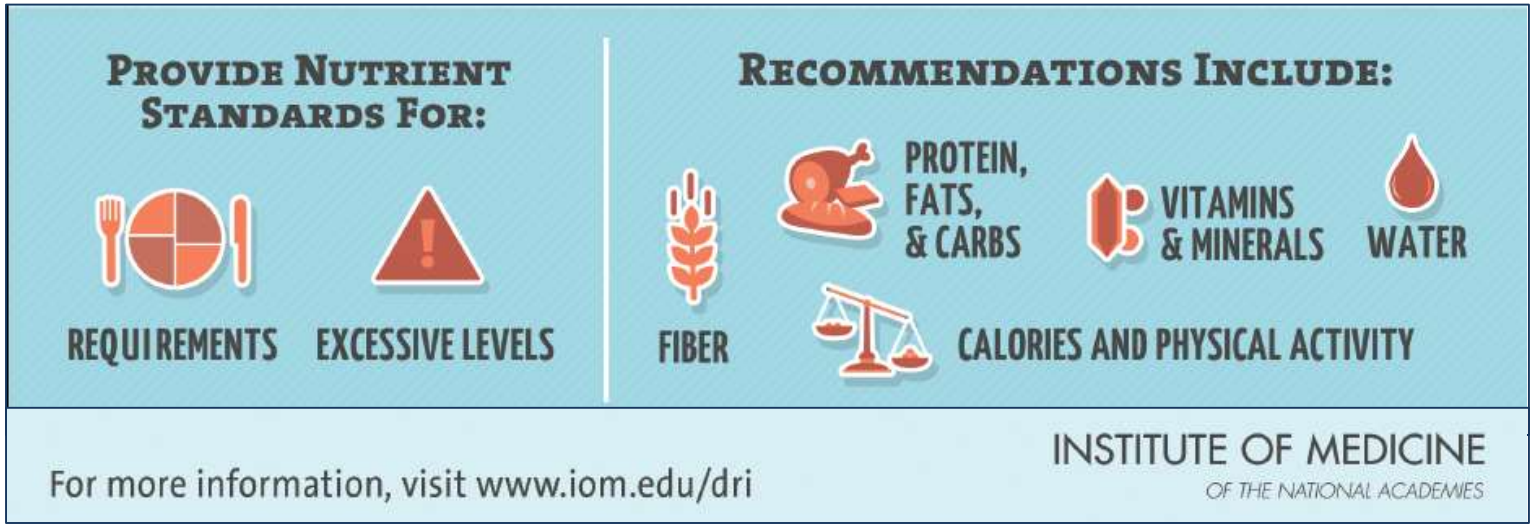


Dietary Reference Intakes

- Specific DRIs
  - Energy
  - Physical activity
  - Carbohydrates, fiber, fats
  - Protein and amino acids
  - Micronutrients
- Special populations
  - Infants, Children, Adolescents
  - Pregnancy
  - Lactation

Introduction to DRI

- Dietary Reference Intakes (DRIs) are a set of nutrient-based reference values
- Developed from concepts used for the Recommended Dietary Allowances (RDAs) and the Recommended Nutrient Intakes of Canada (RNIs)



Introduction to DRI, Continued

- **Developed by Food and Nutrition Board of the National Academies of Science, Engineering, and Medicine**
  - Established in 1940
  - Studies safety and adequacy of the U.S. food supply;
  - Establishes principles and guidelines for good nutrition; and
  - Provides authoritative judgment on the relationships among food intake, nutrition, and health maintenance and disease prevention.

Requirement

- A requirement is defined as the lowest continuing intake level of a nutrient that will maintain a defined level of nutriture in an individual
  - The criteria chosen for adequate nutriture are nutrient specific– typically to prevent deficiency and reduce risk of disease, where possible
  - These criteria may differ for individuals at different life stages
  - These criteria may change as we learn more about indicators of long term health

*Nutriture: Nutritional status, especially with regard to a specific nutrient.

Development of a Nutritional Deficiency

Stage	Depletion Stage	Method of Assessment
1.	Dietary inadequacy	Dietary
2.	Decreased reserves	Biochemical
3.	Decreased levels in body fluids	Biochemical
4.	Decreased function/change in enzyme activity	Anthropometric/ Biochemical
5.	Clinical symptoms	Clinical

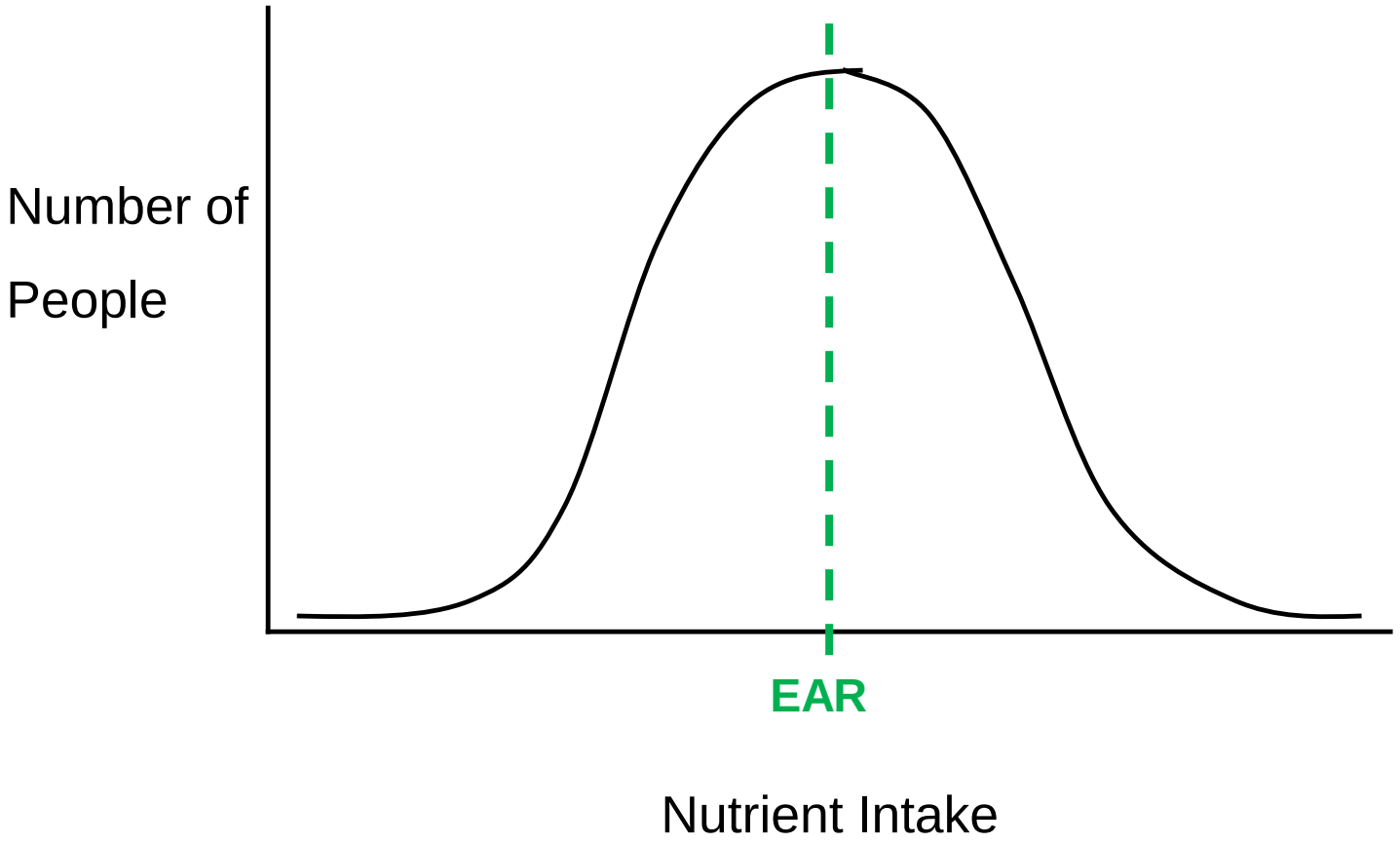
Types of Data Used

- Animal models
  - Used when human data are not available
- Human feeding studies –
  - controlled feeding studies in metabolic wards
- Observational studies
  - Free living subjects, more “real” but less control
- Randomized controlled trials
  - “Best” evidence, not always possible

Estimated Average Requirement (EAR)

- The average daily nutrient intake level estimated to meet the requirement of **half the healthy individuals** in a particular life stage and gender group
  - Metabolic, experimental and observational studies
  - Indicator used for adequacy important in determining requirement

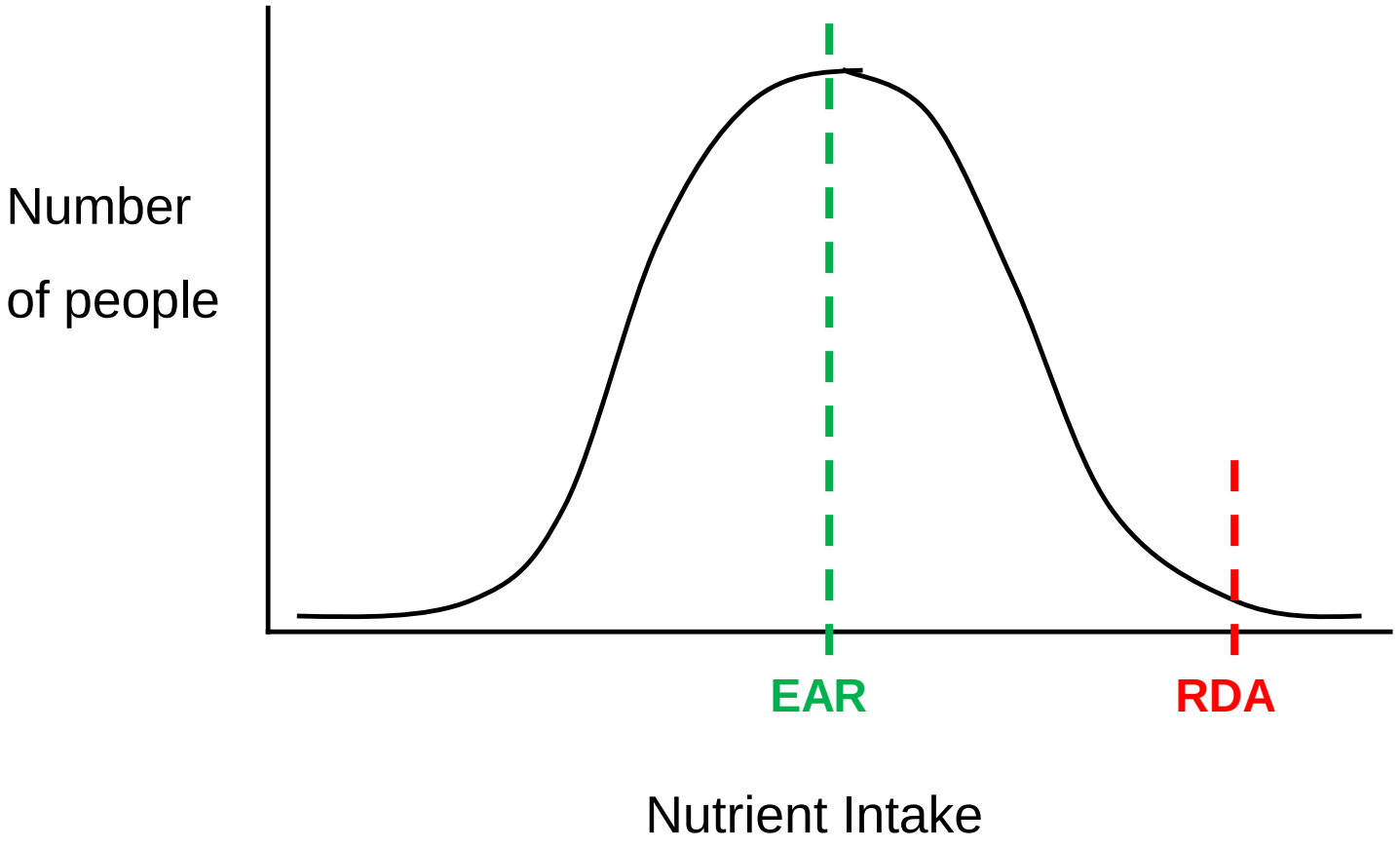
EAR



Recommended Dietary Allowance (RDA)

- The average daily dietary nutrient intake level sufficient to meet the nutrient requirement of **nearly all (97-98%) healthy individuals** in a particular life stage and gender group
- Most RDAs set as Estimated Average Requirement + 2 SD

RDA



Adequate Intake (AI)

- The recommended average daily intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are **assumed to be adequate**
- Used when an RDA cannot be determined (data are inadequate)

Tolerable Upper Intake Level (UL)

- The **highest average daily nutrient intake** level that is likely to pose no risk of adverse health effects to almost all individuals in the general population.
- As intake increases above the UL, the risk of adverse effects increases

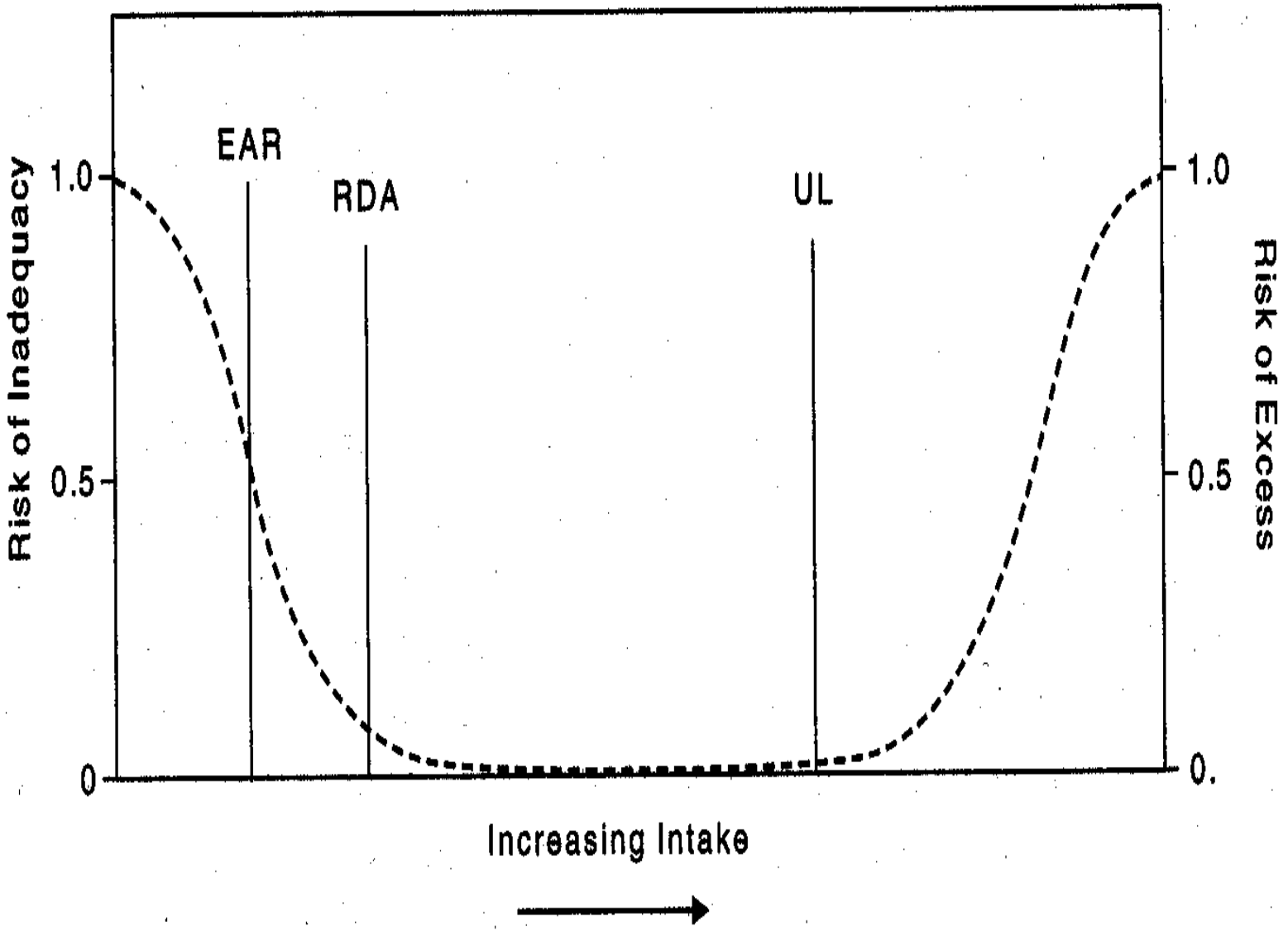
DRIs (cont.)

- All values for EARs, RDAs and AIs represent quantities of nutrients that should be obtained from *foods* typically found in North American diets
- For some nutrients, guidance is provided for diets with altered bioavailability

DRIs (cont.)

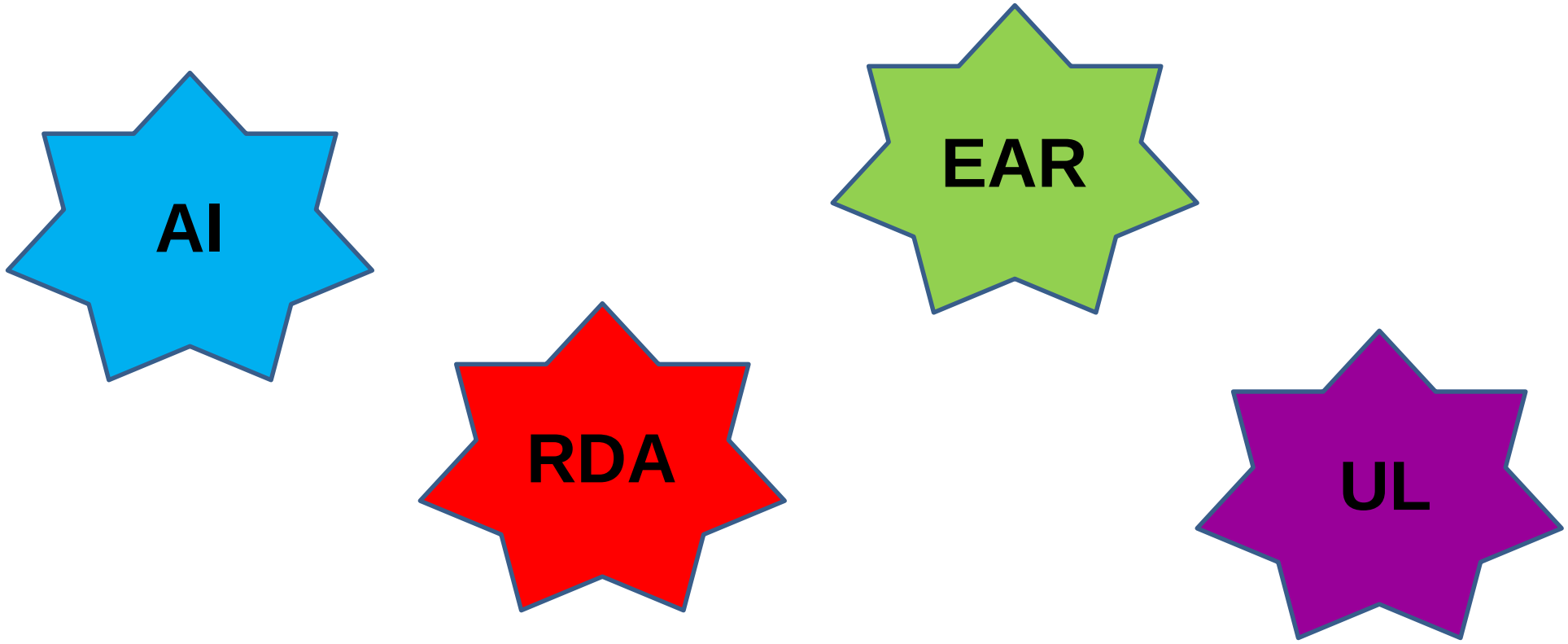
- RDAs and AIs are levels of intake recommended for individuals
  - Meeting them should reduce the individual's risk of developing a condition or outcome related to deficiency
- DRIs apply to healthy people
  - Recommendations may differ for malnourished or ill persons

Figure 1-1


EAR
RDA
UL
1.0
0.5
0
Risk of Inadequacy
1.0
0.5
0.
Risk of Excess
Increasing Intake

Quiz

The EAR for a specific micronutrient is typically (higher or lower) than the RDA for that nutrient



Food Labels - Daily Values

Daily Reference Values (DRVs)

Macronutrients

Nutrition Facts

4 servings per container

Serving size 1 1/2 cup (208g)

Amount per serving

Calories 240

	% Daily Value*
Total Fat 4g	**5%**
Saturated Fat 1.5g	**8%**
Trans Fat 0g	
Cholesterol 5mg	**2%**
Sodium 430mg	**19%**
Total Carbohydrate 46g	**17%**
Dietary Fiber 7g	**25%**
Total Sugars 4g	
Includes 2g Added Sugars	**4%**
Protein 11g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 6mg	35%
Potassium 240mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Reference Daily Intakes (RDIs)

Micronutrients

Use % Daily Value as a Guide

WHAT'S NEW: The Daily Values for nutrients have been updated based on new scientific evidence. The Daily Values are reference amounts of nutrients to consume or not to exceed each day (for adults and children 4 year of age and older) and are used to calculate the % Daily Value.

% Daily Value (%DV) shows how much a nutrient in a serving of the food contributes to a total daily diet. Use the %DV to determine if a serving of the food is high or low in an individual nutrient and to compare food

Nutrition Facts

4 servings per container
Serving size 1 1/2 cup (208g)

Amount per serving
Calories 240

	% Daily Value*
Total Fat 4g	**5%**
Saturated Fat 1.5g	**8%**
Trans Fat 0g	
Cholesterol 5mg	**2%**
Sodium 430mg	**19%**
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Dietary Fiber 7g	**25%**
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Calcium 260mg	20%
Iron 6mg	35%
Potassium 240mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Daily Reference Values (DRV) and Changes

Based on:

- 2000 kcal /day
- 30% kcal as fat (old label)→35% kcal as fat (new label)
- 10% kcal as saturated fat
- 60% kcal as carbohydrates (old label)→55% of kcal as carbohydrates (new label)
- 10% kcal as protein
- Fiber = 14g per 1000 kcal (28g; used to be 25g)
- Added sugars—newly established at 50g (10% of kcal)

Reference Daily Intakes

- The Reference Daily Intakes (RDIs) are the daily intake level of a nutrient that based on the highest RDA for a given nutrient
- The RDI is used to determine the Daily Value of foods, which is what is used on food labels
- These are monitored by the FDA

Nutrition Facts

4 servings per container

Serving size 1 1/2 cup (208g)

Amount per serving	
Calories	**240**
	% Daily Value*
Total Fat 4g	**5%**
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* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

RDIs and the Final Rule

- The FDA issued a Final Rule on changes on the Nutrition Facts Panel
- Changes some of the RDI values
- Original deadline for updating labels was July 28, 2018
- Extended to January 1, 2020 for large companies and January 1, 2021 for small companies

Nutrient	Current Daily Value	Updated Daily Value
Total Fat	65 grams (30% Calories)	78 grams (35% Calories)
Total Carbohydrate	300 grams (60% Calories)	275 grams (55% Calories)
Dietary Fiber	25 grams	28 grams
Added Sugars	*(n/a – no DV)*	50 grams
Sodium	2,400 milligrams	2,300 milligrams
Potassium	3,500 milligrams	4,700 milligrams
Calcium	1,000 milligrams	1,300 milligrams
Vitamin D	10 micrograms	20 micrograms

Poll

Is it lawful for a dietary supplement seller to advertise that their product can be used to treat a disease or health condition?

- Yes, if the claim is supported by scientific evidence
- No, it is not lawful to make that claim

How Are Dietary Supplements Regulated?

- Federal agencies involved
- Laws that apply

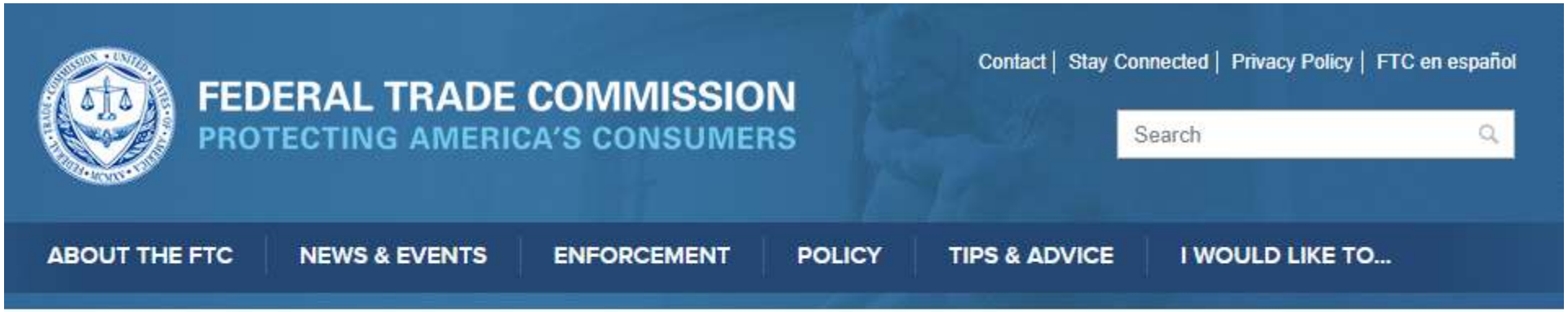
U.S. Food and Drug Administration (FDA)

- Handles regulations of laws related to
  - Foods (except meat, poultry, and egg products)
  - Drugs
  - Processing materials and equipment
- Part of Department of Health and Human Services (HHS)
- Works closely with UDSA - Food Safety and Inspection Service (meat, poultry, eggs)
- **Regulates dietary supplements**

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Federal Trade Commission

- Regulates advertising and marketing of supplements



Home » News & Events » Press Releases » Marketers of Dietary Supplement Amberen Settle FTC Charges Regarding Misleading Weight-Loss and Menopause Relief Claims

Marketers of Dietary Supplement Amberen Settle FTC Charges Regarding Misleading Weight-Loss and Menopause Relief Claims

Office of Dietary Supplement Programs (ODSP)

- Created December 21, 2015
- Elevated the program from its previous status as a division under the Office of Nutrition Labeling and Dietary Supplements
- Aims to remove dangerous products

Nutrition Labeling and Education Act of 1990 (NLEA)

- Nutrition labeling required for most foods
- Voluntary point of purchase nutrition information requested for raw fruits, vegetables and fruits

Exemptions:

- Food served for immediate consumption
- Ready to eat food (deli, bakery)
- Bulk foods
- Medical foods
- Plain coffee and tea

Dietary Supplement Health and Education Act

- Under this act, supplements are effectively regulated by the FDA for Good Manufacturing Practices under 21 CFR Part 111

https://www.youtube.com/watch?v=IV2olDA0w8U

What Are Supplements? (According to the DSHEA)

- Products taken by mouth that contain a "dietary ingredient." Dietary ingredients include vitamins, minerals, amino acids, and herbs or botanicals, as well as other substances that can be used to supplement the diet. (FDA)

- Federal law requires labeling with either "dietary supplement" or a description of the product's dietary ingredient(s) - e.g., “ginseng supplement" or "calcium supplement".

Examples of Dietary Supplements

- Multivitamin/ Multimineral
- Amino Acids
- Botanical/Herbal
- Enzymes

By Raysonho @ Open Grid Scheduler / Grid Engine - Own work, CC0, https://commons.wikimedia.org/w/index.php?curid=45178917

Supplement Labeling

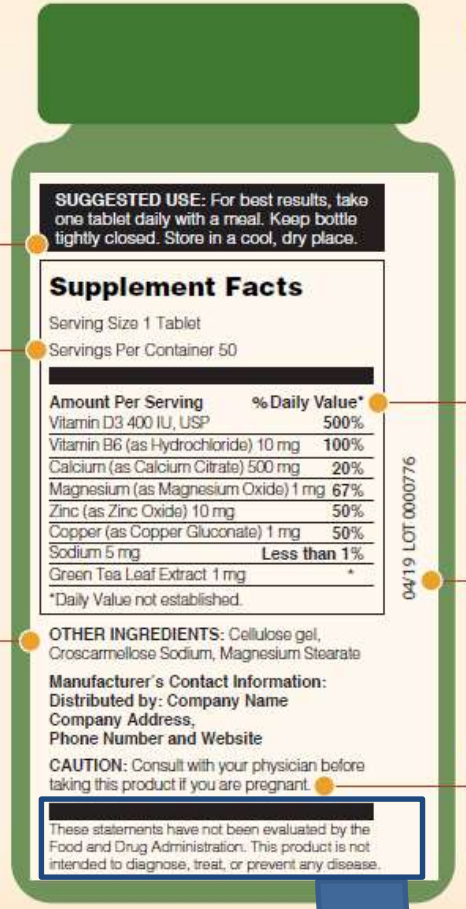
- Supplement labels must contain the following information:
  - The word supplement
  - Net quantity of contents
  - **Supplement Facts Panel** containing serving size information
  - The part of the plant used, if an herb or botanical
  - A complete **list of ingredients** by their common or usual names, either in descending order of prominence or with the source of the dietary ingredient in the "supplement facts" panel following the name of the dietary ingredient - for example, calcium (from calcium carbonate)
  - **Safety information** that is considered "material" to the consequences that may result from the use of the supplement
  - The name and place of business of the manufacturer, packer, or distributor

1 Suggested Use and Serving Size

Dietary supplements are regulated as food, so the recommended amount is listed in terms of "Serving Size"—often in the form of the number of tablets or capsules to be consumed. USP tests each product for **performance** to ensure it will break down and release the ingredients into the body as intended.

2 Supplement Facts Panel

The supplement label lists the individual ingredients contained in each tablet or capsule. USP tests products to **positively confirm the identity** and **purity** of each ingredient.



SUGGESTED USE: For best results, take one tablet daily with a meal. Keep bottle tightly closed. Store in a cool, dry place.

Supplement Facts

Serving Size 1 Tablet

Servings Per Container 50

Amount Per Serving	% Daily Value*
Vitamin D3 400 IU, USP	500%
Vitamin B6 (as Hydrochloride) 10 mg	100%
Calcium (as Calcium Citrate) 500 mg	20%
Magnesium (as Magnesium Oxide) 1 mg	67%
Zinc (as Zinc Oxide) 10 mg	50%
Copper (as Copper Gluconate) 1 mg	50%
Sodium 5 mg	Less than 1%
Green Tea Leaf Extract 1 mg	*

*Daily Value not established.

04/19 LOT 000077G

OTHER INGREDIENTS: Cellulose gel, Croscarmellose Sodium, Magnesium Stearate

Manufacturer's Contact Information:
Distributed by: Company Name
Company Address,
Phone Number and Website

CAUTION: Consult with your physician before taking this product if you are pregnant.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, or prevent any disease.

3 % Daily Value

Where applicable, this value indicates the percent of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) of a dietary ingredient that is in a serving of the product. USP tests each ingredient to ensure the **potency**—that is, the strength or amount of the ingredient—matches what is declared on the label.

4 Expiration Date

USP requires participants to provide expiration date information and tests the product to ensure it will contain the claimed **potency** at the date specified.

5 Cautions & Warnings

Where applicable, this information helps you understand who should avoid or take precautions when taking certain products. USP requires cautionary statements when appropriate as part of participation in our program.

* For additional information about FDA labeling requirements, see http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatory/ DietarySupplements/ucm070597.htm#4-59

Learn more at: www.quality-supplements.org

***These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.**

IMPORTANT FACTS YOU SHOULD KNOW

Calcium is the primary mineral responsible for strong bones.* Our absorbable formula provides Vitamin D to support calcium metabolism and immune health.*

Adequate Calcium and Vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

No Gluten, **No** Yeast, **No** Wheat, **No** Milk or Milk Derivatives, **No** Lactose, **No** Sugar, **No** Preservatives, **No** Artificial Flavor, **No** Sodium.

WARNING: If you are pregnant, nursing or taking any medications, consult your doctor before use. Discontinue use and consult your doctor if any adverse reactions occur.

KEEP OUT OF REACH OF CHILDREN. STORE AT ROOM TEMPERATURE AND AVOID EXCESSIVE HEAT. TAMPER RESISTANT: DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.

Manufactured by Rexall Sundown, Inc.
1111 SW 30th Ave., Deerfield Beach, FL 33442

A0307

N 3 01220 45211 3

ACTUAL SIZE

Prod. No. 45211

02B 819027 FAA ©2011

Since 1903 Rexall®

LIQUID FILLED ABSORBABLE

Calcium 1200 mg plus 1000 IU Vitamin D3

PER SERVING

Bone Health*

60 Softgels
Dietary Supplement

QUALITY GUARANTEED

DIRECTIONS: FOR ADULTS, TAKE TWO (2) SOFTGELS DAILY, PREFERABLY WITH A MEAL. As a reminder, discuss the supplements and medications you take with your health care providers.

Supplement Facts

Serving Size 2 Softgels
Servings Per Container 30

Amount Per Serving		% Daily Value
Calories	15	
Calories from Fat	10	
Total Fat	1 g	2%***
Vitamin D (as D3 Cholecalciferol)	1,000 IU	250%
Calcium (as Calcium Carbonate)	1,200 mg (1.2 g)	120%

***Percent Daily Values are based on a 2,000 calorie diet.

Other Ingredients: Soybean Oil, Gelatin, Glycerin, Soy Lecithin. **Contains <2% of:** Beeswax, Sorbitol, Titanium Dioxide Color.

Quality Guaranteed Lab Tested
Laboratory tested to meet strict quality control standards for potency, purity and disintegration. 100% Quality Guaranteed.

Label Claims

Table 1. Types of FDA Labeling Claims Used on Packaged Foods and Beverages[5]

Type of Claim	Simplified Definition	Examples
Nutrient content claim	A claim on a food product that directly or by implication characterizes the level of a nutrient in the food	"Low fat" "High in oat bran" "Contains 100 calories"
Health claim	Any claim made on the label or in labeling that expressly or by implication (eg, symbols, brand name) characterizes the relationship of any substance to a disease or health-related condition	"Regular exercise and a healthy diet with enough calcium help teens and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life."
Structure/function claim	A claim that describes the effect that a substance has on the structure or function of the body but does not make reference to a disease	"Calcium builds strong bones."

Abbreviation: FDA, Food and Drug Administration.
Source: FDA, Center for Food Safety and Applied Nutrition.[5]

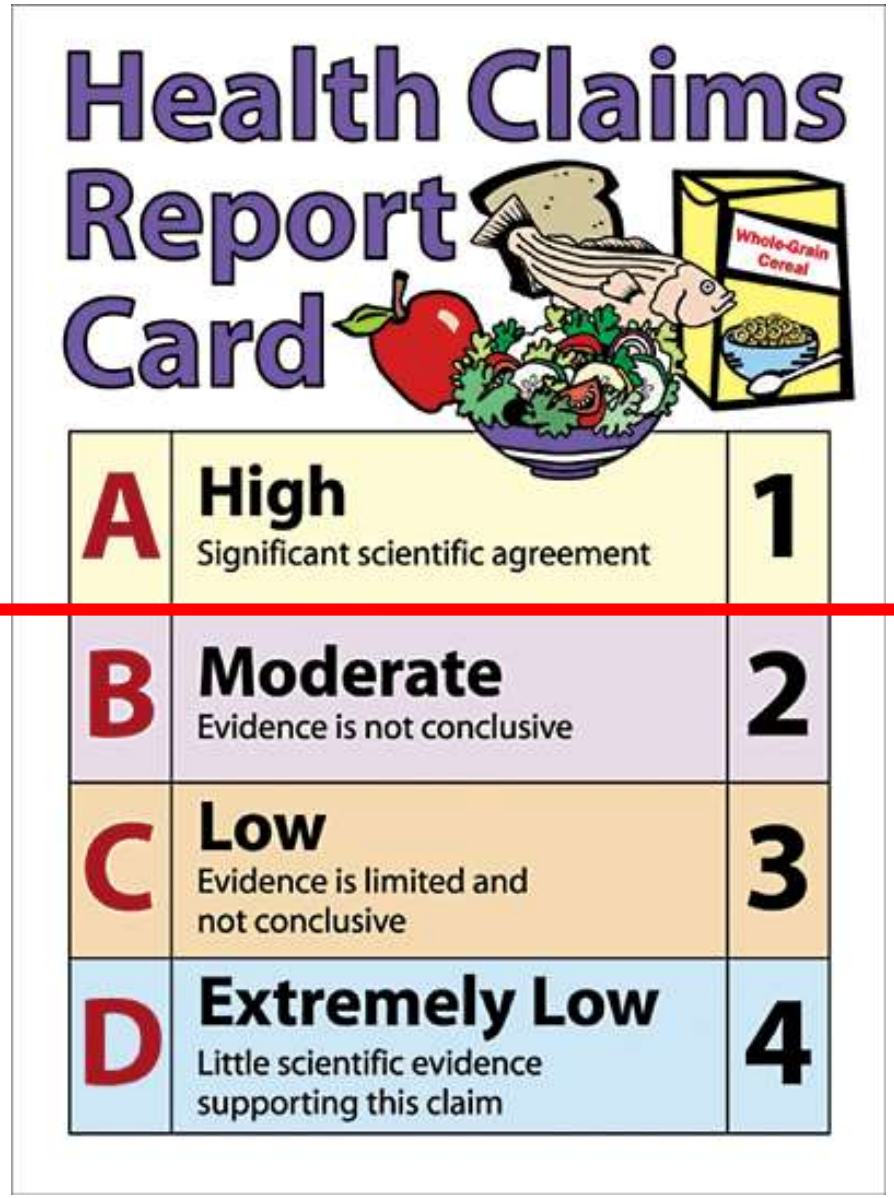
Nutrition Today, Jan/Feb 2010

Claims

- Totality of publicly available evidence supports the claim
  - Randomized clinical trials preferred
  - Use criteria for epidemiological evidence
- “Significant scientific agreement among qualified experts” that the relationship is valid
  - NIH, CDC, National Academy Sciences, Surgeon General, Food and Nutrition Service, Agricultural Research Service etc.
- **Dietary supplements are not included under this rule**

Health Claims and Labeling

Authorized Health Claims: Significant Scientific Agreement



Qualified Health Claims

Reprinted from the International Food Information Council Foundation, Last updated May 23 2014
https://www.foodinsight.org/2004_Qualified_Health_Claims_Research_Executive_Summary

Table 1 **Health claims meeting the standard of significant scientific agreement.**

Substance	Disease	Code of Federal Regulation (CFR) number
Dietary lipids	Cancer	21 CFR 101.73
Fiber-containing grain products, fruits, and vegetables	Cancer	21 CFR 101.76
Fruits and vegetables	Cancer	21 CFR 101.78
Dietary saturated fat and cholesterol	Coronary heart disease	[illegible]
Fruits, vegetables, and grain products that contain fiber, particularly soluble fiber	Coronary heart disease	[illegible]
Soluble fiber from certain foods	Coronary heart disease	[illegible]
~~Soy protein~~	~~Coronary heart disease~~	21 CFR 101.82
Plant sterol/stanol esters	Coronary heart disease	21 CFR 101.83
Sodium	Hypertension	21 CFR 101.74
Folate	Neural tube defects	21 CFR 101.79
Dietary noncariogenic carbohydrate sweeteners	Dental caries	21 CFR 101.80
Calcium, vitamin D	Osteoporosis	21 CFR 101.72

Proposed to be revoked and currently under review (as of March 2018)

Ellwood, K.C. et al. How the US FDA evaluates the scientific evidence for health claims. *Nutrition Reviews*, 2010 68(2):114–121

Example: "Adequate calcium and vitamin D as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life."

Qualified Health Claims

- Emerging evidence for a relationship between a food substance and reduced risk of a disease or health-related condition exists
- But, evidence is limited and does NOT meet FDA significant scientific agreement standards
- Label must include a statement to clarify the level of evidence and/or necessary conditions of use
- Manufacturers can request FDA review to permit the use of the qualified claim

Table 2 **Qualified health claims subject to enforcement discretion.**

Substance	Disease
Tomatoes and/or tomato sauce	Prostate, ovarian, gastric, and pancreatic cancers
Calcium	Colon/rectal cancer and recurrent colon/rectal polyps
Green tea	Breast and prostate cancer
Selenium	Bladder, prostate, and thyroid cancer
Selenium	Certain cancers/anticarcinogenic effects
Antioxidant vitamins (C and E)	Gastric, bladder, colorectal and renal cancer
Antioxidant vitamins (C and E)	Certain cancers
Nuts	Coronary heart disease
Walnuts	Coronary heart disease
Omega-3 fatty acids (EPA and DHA)	Coronary heart disease
B vitamins (B_6, B_{12} and/or folic acid)	Vascular disease
Olive oil (due to monounsaturated fatty acids)	Coronary heart disease
Canola oil (due to unsaturated fatty acids)	Coronary heart disease
Corn oil (due to unsaturated fatty acids)	Heart disease
Phosphatidylserine	Cognitive dysfunction and dementia
Chromium picolinate	Insulin resistance/diabetes
Calcium	Hypertension, pregnancy-induced hypertension, and preeclampsia

List available at https://www.fda.gov/Food/LabelingNutrition/ucm073992.htm

Structure Function Claims

- Applies to conventional foods, dietary supplements, and drugs
- Relate to dietary deficiency- ie: Vit C prevents scurvy
  - Must indicate how widespread the disease is in the U.S.
- How the nutrient or dietary ingredient affects or maintains a structure or function in humans
  - “Calcium builds strong bones”
  - “Fiber maintains bowel regularity”

Structure Function

- Manufacturer is responsible for accuracy
- Supplements must print disclaimer that FDA has not evaluated the claim and that the product **doesn't "diagnose, treat, cure or prevent any disease"**
- Claims may NOT link to disease or state of health leading to disease

Health Claim Violations

- Violation must be reported to FDA
- Violation is investigated
- Letter is written – cease and desist
- Fine is charged if letter is ignored
- If violation is extreme, production may be shut down (extremely rare)

Find out more or report a problem:
https://www.fda.gov/ForConsumers/ProtectYourself/HealthFraud/default.htm

This letter responds to the health claim petition received on June 3, 2016, submitted to the Food and Drug Administration (FDA or the agency) on behalf of Bayer pursuant to Sections 403(r)(4) or 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §§ 343(r)(4) and 343(r)(5)(D)). The petition requested that the agency authorize a health claim characterizing the relationship between the consumption of vitamin D and a reduction in the risk of multiple sclerosis (MS). The petition proposed the following model health claim for use on the label or in the labeling of conventional foods and dietary supplements containing vitamin D:

"Vitamin D may reduce the risk of multiple sclerosis (MS)."

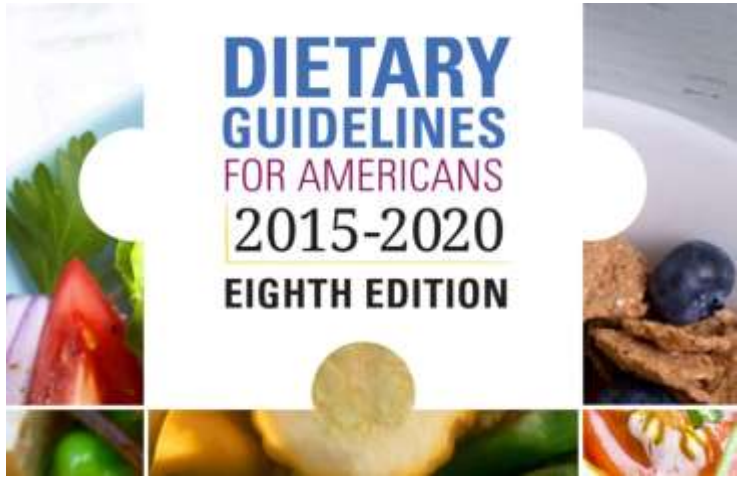
FDA evaluated the scientific evidence provided with the petition and other evidence related to your proposed claim. Based on this review, FDA determined that the scientific evidence supporting the proposed health claim did not meet the "significant scientific agreement" standard under § 403(r)(3)(B)(i) of the Act for conventional food or 21 CFR 101.14(c), which is applicable to dietary supplements. FDA notified you of this decision on September 6, 2016, and we received an email from you on September 7, 2016 stating that your client requests that the petition be changed to a qualified health claim petition on the said relationship. FDA considers this request as the petitioner choosing to seek FDA review of the petition as a qualified health claim petition. Thus, FDA filed the petition on September 9, 2016 as a qualified health claim petition and posted it on the Regulations.gov website for a 60-day comment period, consistent with the agency's guidance for procedures on qualified health claims.[1] The agency received no comments in response to the petition.

Supplements: Dietary Guidelines for Americans

Nutritional needs should be met primarily from foods

> *…dietary components of an eating pattern can have interactive, synergistic, and potentially cumulative relationships, such that the eating pattern may be more predictive of overall health status and disease risk than individual foods or nutrients.*

Fortified foods and dietary supplements may be useful in some cases



When is Supplement Use Encouraged?

- Prenatal Vitamins — to obtain adequate folate and iron
- B12 supplements might be needed to meet the requirements of some Vegetarians and Vegans
- Calcium supplements can be recommended when you can’t get it from the diet
  - Lactose intolerance, milk allergy, older
- Vitamin D when sunlight exposure is low
- People taking medications or with health conditions that change how their body uses nutrients

Why can supplement use be dangerous? CARET Trials (Carotene and Retinol Efficacy)

- Cancer prevention and efficacy of a daily combination of
  - 30 mg beta-carotene and
  - 25,000 IU of retinyl palmitate – (15 times recommended dose of vitamin A)
- 18,314 people at high risk of lung cancer
  - Smokers and workers exposed to asbestos
- CARET was stopped 21 months early
  - definitive evidence of no benefit and
  - substantial evidence for harmful effect on both lung cancer incidence and total mortality

Vitamin E and Cancer, Myocardial Infarction, Eye Disease

- The SELECT study, the Physician's Health Study, and the Alpha-Tocopherol Beta Carotene (ATBC) Study all resulted in no beneficial effects
  - Beta Carotene resulted in increased odds of lung cancer

Why can supplement use be dangerous?

- Supplements are not well-regulated and
- Many may contain doses of nutrients that are well above the RDIs or RDAs
- From the previous webinar, we discussed the **importance of dose**, this holds true with respect to supplements as well!
- Iron in pregnancy with zinc and copper

Why can supplement use be dangerous?

- Poison Control (2017) - adverse reaction to supplements approximately every 24 minutes
  - 2000-2012: 274,998 exposures
- 2013 investigation by the New York State Attorney General's Office
  - Four out of five supplements did not contain what was stated on the label
  - Found fillers such as powdered rice, asparagus, houseplants, etc.

http://www.quality-supplements.org/resources/resource-gallery-infographic

Why can supplement use be dangerous? Drug Interactions

- Some supplements contain compounds which can interact with medications
  - St. John's Wort
  - Goldenseal
  - Black Cohosh
  - Coenzyme Q10

What are some of the drugs affected by St. John's wort (SJW)?

Drug(s) affected	Purpose of affected drug(s)	Adverse effects documented when combined with SJW
Warfarin, Coumarin, Phenprocoumon	anticoagulants	lowering of serum warfarin and phenprocoumon levels; reduced response to warfarin (8-10)
Oral contraceptives	contraceptive, regulator of menstrual cycle	breakthrough bleeding; (no unwanted pregnancies documented) (9,12)
Amitriptyline, nortriptyline	antidepressants	lowering of serum amitriptyline and nortriptyline levels by 22–40 percent (8)
Digoxin	anti-arrhythmic, cardiotonic	lowering of serum digoxin levels (8,9)
Indinavir	HIV protease inhibitor	lowering of serum indinavir levels (13)
Cyclosporin	immunosuppressant (prevent rejection of organ transplant)	lowering of serum cyclosporin levels; acute heart transplant rejection (8,9,14)
SSRIs (selective serotonin reuptake inhibitors)	antidepressants	symptoms of central serotonin excess, especially in elderly patients(15)

Why can supplement use be dangerous? Drug Interactions

- Valerian—may reduce the amount of time it takes to fall asleep
  - increases the sedative effects of depressants, such as alcohol, benzodiazepines, and narcotics
- Melatonin—a hormone that plays a role in sleep which is also available as a supplement
  - According to Mayo Clinic, it’s generally safe, but it does have possible interactions with several medications

Why can supplement use be dangerous?

- Ephedra: A medicinal preparation that has been used for a variety of purposes in traditional Chinese medicine for more than 2000 years
- Dietary Supplements containing an ephedra alkaloid have been found to be unsafe, resulting in ephedra-related deaths
- Due to mounting evidence, the sale of these products was banned in 2004

Why can supplement use be dangerous? Drug Interactions

- Yohimbe—found in the bark of an African evergreen tree and reduces erectile dysfunction
  - Yohimbe hydrochloride made in a lab is not legal to be sold in the US
- Yohimbe has other “uses” but there is not suitable evidence to determine that it is able to do these functions
- Yohimbe taken by mouth is possibly unsafe and has been linked to reports of severe side effects

Why can supplement use be dangerous? Drug Interactions

- People with the following conditions should not take yohimbe:
  - pregnancy and breast-feeding;
  - bleeding conditions; schizophrenia; prostate problems; post-traumatic stress disorder; liver disease; kidney disease; high blood pressure or low blood pressure; chest pain or heart disease; diabetes
  - anxiety; depression;
  - surgery
- Major interactions for medications for depression, specifically MAOIs;
- Moderate interactions with medications that control blood pressure and tricyclic antidepressants; also Narcan and certain stimulant drugs

Brazilian Rainbow Diet Pills

Discovery

- Physician notices patients with similar symptoms
- These patients are all of a similar background—recent Brazilian immigrants
- Physician finds out these patients have all been taking Brazilian Rainbow Diet Pills, imported from Brazil

Research

- Conducts a study at health clinics and churches with a highly Brazilian immigrant population
- Finds that of those taking these pills nearly 2/3rds had symptoms
- These symptoms included heart palpitations, sweating, anxiety, and exhaustion
- Analyzes the contents of the Rainbow Diet Pills and finds they contain amphetamines, thyroid hormones, diuretics, benzodiazepines, and anti-depressants

Outcome

- Published these results in the Journal of Immigrant and Minority Health
- Due to low readership of the journal, the author also reached out to several reporters to share his findings
- Press was worldwide, including a front page story in a Brazilian newspaper
- As a result, the Brazilian government has since banned the supplement

FTC: Signs of Supplement Fraud

- Claims that one product does it all and cures a wide variety of health problems.
- Suggestions the product can treat or cure diseases.
- Words like scientific breakthrough, miraculous cure, exclusive product, secret ingredient, or ancient remedy.
- Misleading use of scientific-sounding terms: “Molecule multiplicity”, “thermogenesis”
- Phony references to Nobel Prize winning technology or science.
- Undocumented testimonials by patients or doctors.
- Limited availability and a need to pay in advance.
- Promises of no-risk “money-back guarantees”.

Questions about Supplements in Classes

- DON’T give participants advice about whether to take supplements
- DO:
- Encourage participants to inform health professionals about all supplement intake and any side effects
  - A professional such as a pharmacist can check for known medication interactions
- Inform participants about reliable sources of information on supplements
- Always base information on the *Dietary Guidelines for Americans*

Websites with **Reliable** Dietary Supplement Information

Office of Dietary Supplements https://ods.od.nih.gov/

National Center for Complementary and Integrative Health (NCCIH)
https://nccih.nih.gov/health/herbsataglance.htm

USP - United States Pharmacopeia
http://www.quality-supplements.org/

ConsumerLab - https://www.consumerlab.com/

NSF International - https://info.nsf.org/Certified/Dietary/

Nutrition Information

UCDAVIS

DEPARTMENT of NUTRITION

http://nutrition.ucdavis.edu

CENTER for NUTRITION in SCHOOLS

CONNECTING FOOD, HEALTH, AND LEARNING

http://cns.ucdavis.edu

Next *Nutrition Updates* Webinar

February 5, 2019

11:00 AM to 12:30 PM