



FDA: Teaching Science Concepts and Inquiry with Food

Dietary Supplements

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Protecting Consumers, Promoting Public Health

U.S. Food and Drug Administration

Broad Responsibilities

Varied Products

- ◆ *Common food and food ingredients*
- ◆ *Complex medical & surgical devices*
- ◆ *Therapeutic pharmaceuticals*
- ◆ *Radiation-emitting consumer and medical products*

Varied Regulatory Approaches

- ◆ *Review of safety and efficacy for new drugs and medical devices*
- ◆ *Performance standards for x-ray machines & microwave ovens*
- ◆ *No prior approval for cosmetics and dietary supplements*


Benefits vs. Risks



Safe, Wholesome, Sanitary Foods



Safe And Effective



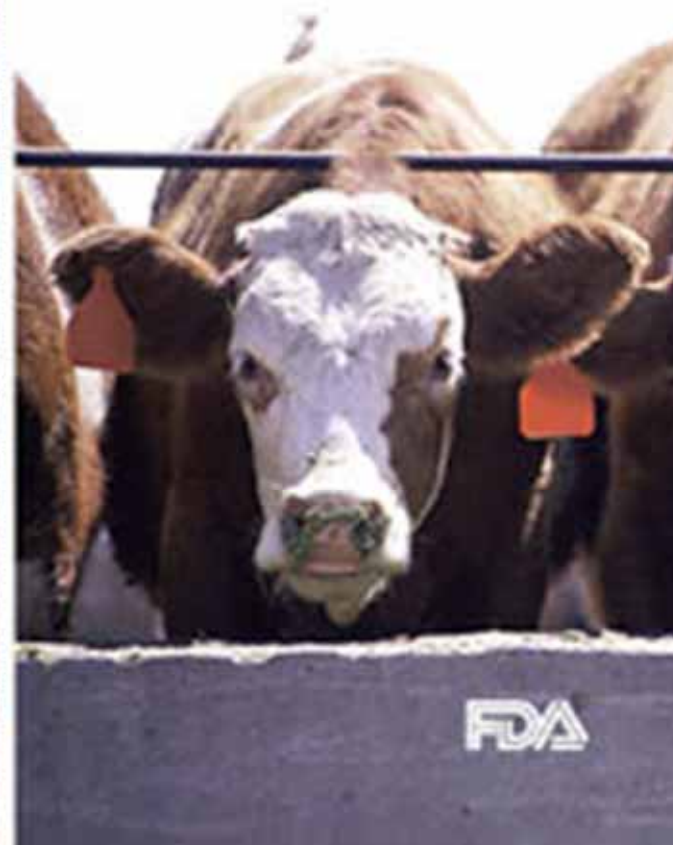
Medicines

Biologics

Medical Devices



Safe And Effective Animal Drugs



Safe Consumer And Medical Radiation Products



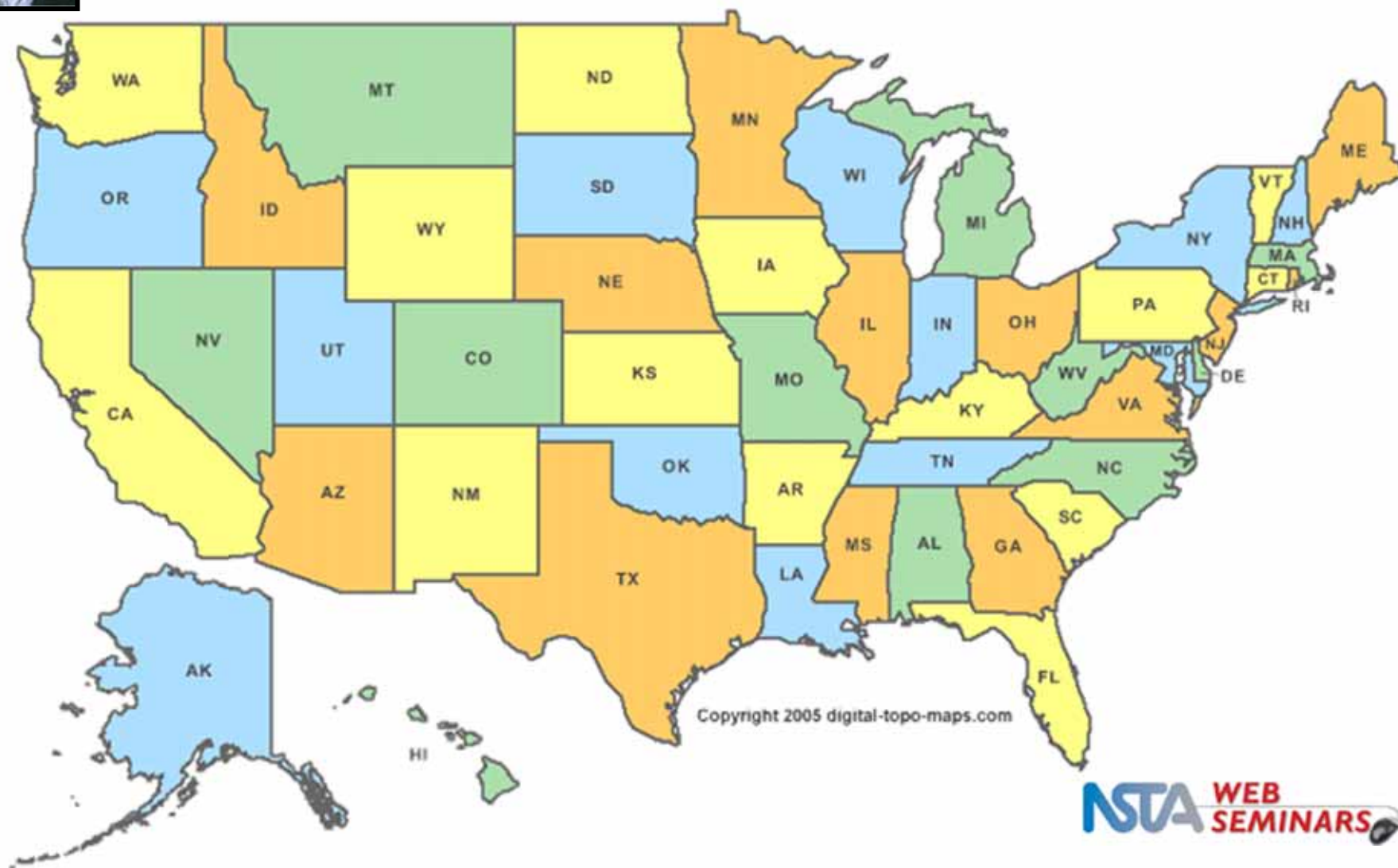
FDA

Safe Cosmetics



Where do you think FDA offices are located?

Use clip art to show the location.



FDA In Your Neighborhood





Pause Two Minutes for Questions



Dietary Supplement Health and Education Act of 1994 (DSHEA)

- ◆ Public Law 103-417
- ◆ Signed into law October 25, 1994
- ◆ Congressional Record at 108 Stat. 4325



Intent of Congress

- ◆ Limit impediments to marketing and promotion of dietary supplements
- ◆ Promote availability of supplements to consumers to improve health
- ◆ Promote disseminating information



DSHEA Poll Question



- Under DSHEA were supplements exempted from regulation?

✓ Yes

✗ No

What DSHEA Didn't Do

- ◆ Changed way we regulate supplements
 - ◆ Did not exempt supplements from regulation
 - ◆ Did not limit FDA's ability for enforcement
 - ◆ Did not undermine integrity of drug development incentives



Dietary Supplements Overview

- ◆ General regulatory framework
- ◆ Claims
- ◆ General safety

Interpreting DSHEA

- ◆ No legislative history
 - ◆ Plain language of the statute
 - ◆ Statement of Agreement
 - ◆ Congressional Findings
- ◆ Balance Congressional intent and consumer protection



What is a dietary supplement?

1)

2)

Please Raise your hand to volunteer



What is a dietary supplement?

“...a product (other than tobacco) intended to supplement the diet that bears or contains one or more” designated ingredients

21 U.S.C. 321(ff)(1)



“Intended to supplement the diet”

- ◆ Diet: “usual food or drink of man”
- ◆ Supplement: “augment diet to promote health and reduce risk of disease”

Dietary Ingredients

- ◆ Vitamin, Mineral, Amino acid
 - ◆ Not limited to “nutritionally recognized”
- ◆ Herb or other botanical
 - ◆ Any part of a plant
- ◆ Dietary substance for use by man to supplement the diet by increasing the total dietary intake
- ◆ Concentrate, metabolite, constituent, extract, or combination of any ingredient above



“Dietary substance for use by man”

- ◆ “of or pertaining to the diet” and “usual food or drink of man”
 - ◆ Mere presence in the diet does not confer status as “dietary substance”
 - ◆ Not include harmful substances
 - ◆ For use in diet of man

Other Requirements

- ◆ A product that is intended for ingestion
- ◆ Pill, capsule, liquid, powder, “other”
- ◆ Not represented for use as conventional food
 - ◆ Delivery system may resemble conventional food forms
- ◆ Not a sole item of a meal or diet
- ◆ Labeled a “dietary supplement”

21 U.S.C. 321(ff)(2)



In the previous slide, the word “ingestion” refers to any route taken into the body.



Yes



No

“Intended for ingestion”

- ◆ Ordinary and plain meaning of “ingestion”
- ◆ Take into the stomach and gastrointestinal tract

US v. Ten Cartons, Ener-B Nasal Gel,
888 F. Supp. 381, 393-94
(E.D.N.Y.), aff’d, 72 F.3d 285 (2d
Cir. 1995)

“Represented as conventional food”

- ◆ Think “how is it to be used” or “what is it a substitute for”
 - ◆ named a snack or uses another common or usual food name
 - ◆ uses a standardized food name
 - ◆ uses label representations/pictures that suggest conventional food uses

“Represented as conventional food” - Examples

- ◆ “Supplement soups”
(Jun. 21, 1999 ltr., Hain Food Group)
- ◆ “Cereals”
(Jun. 5, 2001 WL, US Mills, Inc.)
- ◆ Chewing gum
- ◆ Bottled water
(Jun. 7, 2001 ltr., Better Health Labs)
- ◆ Beverages/Drinks?

Drug Exclusion Clause

Does not include an article that is an:

- ◆ approved new drug, antibiotic, or biologic
- ◆ authorized investigational new drug, antibiotic, or biologic

UNLESS “Marketed as a dietary supplement or as a food before such approval or authorization”

- ◆ Relevant to OTCs with an approved NDA or IND under 21 U.S.C 351

21 U.S.C. 321(ff)(3)

Pharmanex, Inc. v. Shalala, No. 2:97CV262K, 2001 WL 741419 (D. Utah, Mar. 30, 2001)



Pause Two Minutes for Questions

New Dietary Ingredients (NDIs)

- ◆ Those that were not marketed as a dietary supplement or a food prior to Oct. 15, 1994
- ◆ FDA notification required before introducing a product with an NDI
 - ◆ 21 C.F.R § 190.6
- ◆ No authoritative list of “old” dietary ingredients

21 U.S.C. 350(b)

New Dietary Ingredients (NDIs)

- ◆ The dietary supplement contains only dietary ingredients that have been present in the food supply as an “article used for food” in a form in which the food has not been chemically altered
 - ◆ “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. [21 U.S.C. 321 (f)]
 - ◆ “chemically altered” – look to Congressional Record

21 U.S.C. 350b (a)(1)

New Dietary Ingredients (NDIs)

- ◆ The manufacturer or distributor submits a **premarket notification** to FDA that contains history of use or other evidence of safety establishing that the NDI “**will reasonably be expected to be safe**” when used as recommended/ suggested in the product’s labeling



Dietary Supplement Claims

- ◆ Structure/Function Claims

- ◆ Health Claims

 - Significant Scientific Agreement
 - Qualified Health Claims

Disease

- ◆ Drug: article intended to treat, cure, prevent, mitigate or diagnose a disease
- ◆ Disease or Health-Related Condition
“Damage to an organ, part, structure, or system of the body such that it does not function properly (e.g. Coronary heart disease, or a state of health leading to such dysfunctioning (e.g. hypertension)”

(21 CFR 101.14(a)(5))/21 CFR
101.93(g)(1)



“Dietary Supplement Claims”

◆ DSHEA (1994)

- ◆ *Classical nutrient deficiency disease*
- ◆ *Effect on Structure or function of the body*
- ◆ *Mechanism of effect on structure/function*
- ◆ *General well-being*

[21 U.S.C. 343 (r)(6)]

STRUCTURE/FUNCTION REGULATION

- ◆ January 6, 2000 Federal Register (65 FR 1000) [21 CFR §101.93]
- ◆ Not limited to serious diseases
- ◆ Act doesn't distinguish minor vs. serious conditions
 - ◆ Congress was silent on this matter



Caveat for Use of the Rule to Define Disease Claims

- ◆ Context is CRITICAL
 - ◆ A disease claim may be explicit or implicit
 - ◆ Not always possible to have absolute distinctions between disease and non-disease claims
 - ◆ Need to consider all information in labeling and elsewhere
 - ◆ Few claims are likely to be always or never appropriate

Please Match the Expressed Disease
with the Implicit Claim by using clip art.

Arthritis ✓

Cancer ✗

BPH 😊

Fibromyalgia



For individuals
experiencing
constant muscle
ache and
stiffness,
fatigue, and
sleeping
problems

Alleviates
frequent
urinating in
older men

Alleviates
degeneration of
discs and joints;
Reduces joint
pain and
inflammation

Prevent
spread of
neoplastic
cells



Disease Claims Define the Product

Expressed

Arthritis inflammation

Cancer

BPH

Fibromyalgia

Implicit

Alleviates degeneration of discs and joints; Reduces joint pain

Prevent spread of neoplastic cells

Alleviates frequent urinating in older men

For individuals experiencing constant muscle ache and stiffness, fatigue, and sleeping problems

Disease Claims Define the Product

Disease

Alternative to prozac
Help insulin maintain blood sugar
Helps statin drugs lower cholesterol
Reduces pain and inflammation
Toxemia in pregnancy
Supports antiviral response
Antibiotic; Analgesic
Alleviates colon ulcers for individuals taking doxorubicin

Structure/Function

Alternative to anabolic steroids
Replace potassium losses associated with diuretic drugs
Maintains normal blood cholesterol
Maintains joint health and comfort
Alleviates ordinary morning sickness associated with pregnancy
Supports the immune system
Energizer, adaptogen
Supports healthy colon function



Pause Two Minutes for Questions

Dietary Supplement Claims

- ◆ NLEA Health Claims (1990)
 - ◆ Characterize the relationship between the presence or level of a substance and a disease or health-related condition
 - ◆ Claim or elements may be explicit or implicit
 - ◆ New claims established by petition and rule making. Significant Scientific Agreement validity standard applies

[21 U.S.C. 343 (r)(1) – r(5)]

Dietary Supplement Claims

- ◆ Health Claims (Continued)
 - ◆ Required Minimum Nutrient Content
 - ◆ 10% DV/serving of vitamins A & C, calcium, iron, protein, fiber
 - ◆ 14 authorized SSA health claims

[21 U.S.C. 343 (r)(1) – (5)]

Dietary Supplement Claims

◆ QUALIFIED HEALTH CLAIMS

- ◆ Do not meet the SSA validity standard
- ◆ 8 authorized qualified health claims
 - ◆ Selenium and cancer
 - ◆ Antioxidant vitamins and cancer
 - ◆ Nuts and heart disease
 - ◆ Walnuts and heart disease
 - ◆ Omega-3 fatty acids and heart disease
 - ◆ B vitamins and vascular disease
 - ◆ Phosphatidylserine and dementia
 - ◆ 0.8 mg Folic acid and birth defects

Amendment for Safety

- ◆ A dietary supplement is adulterated if:
 - ◆ Presents unreasonable risk of illness or injury conditions of use recommended or suggested
 - ◆ Inadequate information for assurance of safety for new dietary ingredients
 - ◆ Secretary declares to pose an imminent hazard
 - ◆ Contains a dietary ingredient that is poisonous or deleterious

21 U.S.C. 342(f)(1)

Amendment for Safety

- FDA shall bear the burden proof to show that a dietary supplement is adulterated

PLSC 2 1

Amendment for Safety

- ◆ Ephedrine Alkaloids (February 11, 2004 Federal Register; 69 FR 6787)
- ◆ Adulteration determination based on:
 - ◆ evidence on ephedrine pharmacology
 - ◆ peer-reviewed scientific literature on ephedrine safety and effectiveness
 - ◆ adverse event reports
 - ◆ seminal report by an independent institute
 - ◆ public comment on ephedrine-associated health risks.

Summary

- ◆ DSHEA remains a dynamic law subject to interpretation
- ◆ FDA's implementation intended to balance Congress' intent and consumer protection
- ◆ No legislative history
 - ◆ Plain language of the statute
 - ◆ Statement of Agreement
 - ◆ Congressional Findings
 - ◆ Interpretation of Court Decisions and relevant case law
- ◆ November 9, 2004 Implementation and Enforcement Strategy (69 FR 64957)
(<http://www.fda.gov/bbs/topics/news/2004/NEW01130.html>)



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