FDA: Teaching Science Concepts and Inquiry with Food

Dietary Supplements

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Tuesday, April 28, 2009
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
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

321(ff)(1)21 U.S.C.
“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

“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)

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.

21 U.S.C. 350b (a)(2)
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)]
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
<table>
<thead>
<tr>
<th>Arthritis ✓</th>
<th>Cancer ×</th>
<th>BPH 😊</th>
<th>Fibromyalgia 🤓</th>
</tr>
</thead>
<tbody>
<tr>
<td>For individuals experiencing constant muscle ache and stiffness, fatigue, and sleeping problems</td>
<td>Alleviates frequent urinating in older men</td>
<td>Alleviates degeneration of discs and joints; Reduces joint pain and inflammation</td>
<td>Prevent spread of neoplastic cells</td>
</tr>
</tbody>
</table>
# Disease Claims Define the Product

<table>
<thead>
<tr>
<th>Expressed</th>
<th>Implicit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthritis inflammation</td>
<td>Alleviates degeneration of discs and joints; Reduces joint pain</td>
</tr>
<tr>
<td>Cancer</td>
<td>Prevent spread of neoplastic cells</td>
</tr>
<tr>
<td>BPH</td>
<td>Alleviates frequent urinating in older men</td>
</tr>
<tr>
<td>Fibromyalgia</td>
<td>For individuals experiencing constant muscle ache and stiffness, fatigue, and sleeping problems</td>
</tr>
</tbody>
</table>
## Disease Claims Define the Product

<table>
<thead>
<tr>
<th>Disease</th>
<th>Structure/Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alternative to prozac</td>
<td>Alternative to anabolic steroids</td>
</tr>
<tr>
<td>Help insulin maintain blood sugar</td>
<td>Replace potassium losses associated with diuretic drugs</td>
</tr>
<tr>
<td>Helps statin drugs lower cholesterol</td>
<td>Maintains normal blood cholesterol</td>
</tr>
<tr>
<td>Reduces pain and inflammation</td>
<td>Maintains joint health and comfort</td>
</tr>
<tr>
<td>Toxemia in pregnancy</td>
<td>Alleviates ordinary morning sickness associated with pregnancy</td>
</tr>
<tr>
<td>Supports antiviral response</td>
<td>Supports the immune system</td>
</tr>
<tr>
<td>Antibiotic; Analgesic</td>
<td>Energizer, adaptogen</td>
</tr>
<tr>
<td>Alleviates colon ulcers for individuals taking doxorubicin</td>
<td>Supports healthy colon function</td>
</tr>
</tbody>
</table>
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

21 USC 342(a)
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.elluminate.com
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