FDA Regulation of Claims on Dietary Supplement and Food Products

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Topics

• FDA Overview
• What are “claims”
• Why claims matter
• Categories of claims
• Regulatory requirements for types of claims
• Principles for distinguishing between types of claims
What is the U.S. FDA

• The Food & Drug Administration (FDA) is a federal science-based law enforcement agency mandated to protect the public health
• The agency has approximately 10,000 employees, including scientists, inspectors, medical doctors and other professionals
• FDA’s budget is approximately $1.2 billion, or about $4 a year per taxpayer
• FDA is an agency of the U.S. Department of Health and Human Services
What Does FDA Regulate

- Human and Veterinary Drugs
- Biological Products
- Medical Devices
- Electronic Products that Emit Radiation
- Foods
- Dietary Supplements
- Cosmetics
FDA Organization & Operations

- Commissioner of Food & Drugs
- Headquarters in suburban Maryland
  - Office of the Commissioner
  - Five Product Based Centers
  - Office of Regulatory Affairs
- Field Offices throughout the United States
- Foreign Inspections by FDA investigators
FDA In Your Neighborhood
Foods: Who Does What

• U.S. Department of Agriculture (USDA) -- not FDA -- regulates most meat and poultry and some egg products

• Main regulatory components
  – Food Safety and Inspection Service (FSIS)
  – Animal Plant Health Inspection Service (APHIS)
    • Plant and animal pests and diseases
    • Environmental safety of genetically modified crops and plants
FDA CFSAN Responsibilities

- Safety and labeling of 80% of the national food supply, including seafood products, dairy products, and most game meats
- Dietary supplements, vitamins, and herbal products
- Infant formulas and medical foods
- Conducting pre-market review of food additives, food coloring, and genetically modified foods
- Enforcing compliance with pesticide tolerances set by the Environmental Protection Agency
- Cosmetics
What Are “Claims”

- Claims include statements on product “label”
- “Labeling” is also important
- “Labeling” includes the label on the product itself and any written, printed, or graphic materials part of the packaging or accompany the product
  - Can include promotional materials
Why Do “Claims” Matter

• Under FDA law, “claims” determine what a product is
• Congress adopted broad definitions of “drug” “food” “dietary supplement” and other products subject to FDA regulation
• FDA -- and the courts -- use these definitions to determine whether and how FDA can regulate a product
What is a “Food”

- The term “food” means
  - articles used for food or drink for man or other animals,
  - chewing gum, and
  - articles used for components of any such article
What is a “Drug”

- An article “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals” or
- An article “(other than food) intended to affect the structure or any function of the body of man or other animals”
Claims Matter

• In general, use of “disease” claims will cause a “food” to be regulated as a “drug”
• Drugs are subject to rigorous pre-market approval requirements
• But Congress created some exceptions
  – Nutrition Labeling and Education Act 1990
  – Dietary Supplement Health and Education Act 1994
  – Food & Drug Modernization Act 1997
What is a “Drug” Claim

• A claim to treat, reduce the symptoms of, or mitigate an existing disease is exclusively a drug claim
• Some -- but not all -- prevention claims are exclusively drug claims
• If the claim is health-related -- or intended to reduce the risk of a disease -- then subject to the NLEA regulatory framework
  – Product is regulated as a food or dietary supplement rather than as a drug
  – But must be a “dietary supplement” or “food”
What is a “Dietary Supplement”

• A product intended to supplement the diet that bears or contains one or more of the following dietary ingredients
  – a vitamin
  – a mineral
  – an herb or other botanical
  – an amino acid
  – a dietary substance for use by man to supplement the diet by increasing the total dietary intake
  – a concentrate, metabolite, constituent, extract, or combination of any ingredient above
What is a “Dietary Supplement”

• A dietary supplement means a product that -
  – is intended for ingestion by mouth
  – is not represented for use as a conventional food
  or as a sole item of a meal or the diet, and
  – is labeled as a dietary supplement

• A dietary supplements is also a food
  – unless a claim makes it a drug
Requirements for Dietary Supplements

• Must not have a “significant or unreasonable risk of illness or injury”
• Must not include “poisonous or deleterious substances” or be “unfit for food”
• Must have truthful and informative labeling that is not false or misleading in any respect
• Must comply with applicable requirements for any claims
• Must not have “drug” claims
• New dietary supplement good manufacturing practice regulations being finalized by FDA
Permissible Claims

- Claims that can be used on foods and dietary supplements fall into three categories
  - Nutrient content claims
  - Structure/function claims
  - Health claims
Nutrient Content Claims

• Characterize the level of a nutrient in a food in accordance with FDA’s authorizing regulations

• Purpose is to help ensure that descriptive terms -- such as high, low, free -- are used consistently and are meaningful to consumers
  – Specific rules for calories, fat, saturated fat, cholesterol, sodium, sugars
  – General rules for use of words such as light, reduced, more, less, lean, modified, high potency
Structure Function Claims

• Describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans

• May characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function

• May describe general well-being from consumption of a nutrient or dietary ingredient
Health Claims

- Describe a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health-related condition
- Have two essential components
  - a substance (whether a food, food component, or dietary ingredient) and
  - a disease or health-related condition
- Do not include disease treatment or mitigation of symptoms of disease conditions
NLEA Authorized Health Claims

- Standard for agency review is whether “significant scientific agreement” supports the health claim
  - Based on an extensive review of the scientific literature relating to the health claim
- Generally the result of a health claim petition to FDA
- If FDA finds that the health claim meets the significant scientific agreement standard, the health claim is authorized by a regulation (requires rulemaking)
Authoritative Statements

- Health claims based on “authoritative statements” are permitted for foods
  - Not permitted for dietary supplements
- Need to be from a scientific body of the U.S. Government or the National Academy of Sciences
- Require 120 day notification to FDA prior to marketing
Qualified Claims

- Resulted from various First Amendment challenges
- Are permitted when there is emerging evidence for a relationship between a food, food component, or dietary supplement and reduced risk of a disease or health-related condition
  - Evidence may not be well enough established to meet the significant scientific agreement standard
- Include qualifying language to indicate that the evidence supporting the claim is limited
Levels of Qualified Health Claims

- In 2003, FDA explained standard qualifiers that may be used by the agency when it evaluates health claim petitions that do not meet the significant scientific agreement standard
- **B level** -- “Although there is scientific evidence supporting the claim, the evidence is not conclusive”
- **C level** -- “Some scientific evidence suggests . . . however, FDA has determined that this evidence is limited and not conclusive”
- **D level** -- “Very limited and preliminary scientific research suggests . . . FDA concludes that there is little scientific evidence supporting this claim”
Types of Claims

• Dietary Guidance
• Drug-only Claim
• Health Claim
  – Authorized
  – Authoritative statement
  – Qualified
• Nutrient Content Claim
• Structure/Function Claim
Distinguishing Between Claims

• Generally, if a claim is not permissible as a structure function claim, it is a disease claim
  – Some disease claims may be eligible to be made as health claims - e.g., reduce risk of a disease
  – Other disease claims may be made only as drug claims - e.g., reduce symptoms of a disease

• Cannot make explicit or implicit disease claims as structure-function claims
Basic Principles

• Not always possible to draw a bright line between structure/function and disease claims
  – Context is important
  – Case-specific determinations based on all the information in the labeling
• FDA has ten criteria for evaluating whether a claim is a permissible structure-function claim
Effect on a Disease or Class of Diseases

• A claim is a disease claim if it mentions a specific disease or class of diseases.

• A statement also is a disease claim if it implies that it has an effect on a specific disease or class of diseases by using descriptions of the disease state.
Effect on Characteristic Signs or Symptoms of Disease Using Scientific or Lay Terminology

• Are the signs and symptoms related to a disease?
• Do they permit the inference that the product is intended to affect that disease?
• Some signs and symptoms are so tied to a particular disease that any claim implies disease treatment
  – “inhibits platelet aggregation”
• Others are associated with a wide range of diseases and non-disease states
  – “improves absentmindedness”
Effect on Characteristic Signs or Symptoms of Disease Using Scientific or Lay Terminology

• Context is important
  – Compare “maintain cholesterol levels that are already in the normal range” with “reduces cholesterol”

• Words that *might* constitute a disease claim depending on context
  – “restore” “support” “maintain” “raise” “lower” “promote” “regulate” or “stimulate”

• Words that are disease claims
  – “prevent” “mitigate” “diagnose” “cure” or “treat”
Effect on a Condition Associated with a Natural State or Process

- Some natural states or processes such as aging, menopause, and the menstrual cycle are not themselves diseases, but can be associated with abnormal conditions that are diseases
- Is the condition uncommon?
- Can the condition can cause significant or permanent harm?
Product Name, Formulation, Use of Pictures

- Product name that includes the name -- or a recognizable portion of the name -- of a disease
- Name of an ingredient that has been regulated as a drug or is well known for treating or preventing disease
- General statements about health promotion and disease prevention
  - Compare “A good diet promotes good health and prevents the onset of disease” with “Promotes good health and prevents the onset of disease”
- Pictures and symbols can be used if do not imply a disease claim (e.g., photo of abnormal tissue or organ)
Belongs to a Product Class Intended for Disease Treatment, Prevention, etc.

- Product class so strongly associated with treating and preventing diseases that use is a disease claim
  - Analgesics, antibiotics, antidepressants, antimicrobials, antiseptics, antivirals, or vaccines
- Other product classes may be associated with diseases and with structure/function effects
  - Context is key
  - “Diuretic that relieves temporary water-weight gain”
Substitute for Existing Therapy for a Disease

• Implied claim if claim product is a substitute for a drug or other therapy for disease, or
• Has fewer side effects than a therapy for disease
• *But* can make comparisons if the drug is not intended to treat or prevent disease
  – That is, is a drug intended to affect the structure or function of the body
Augment a Therapy or Drug Intended to Treat Diagnosis or Prevent a Disease

- Such claims are disease claims
- A dietary supplement may state that it is useful in providing nutritional support -- as long as that claim doesn't imply an effect on a disease
- In general, mentioning the name of a specific therapy, drug, or drug action will associate the claim with the intended use of the therapy, drug, or drug action and be a disease claim.
A Role in Body’s Response to a Disease or a Vector of Disease

• A claim that a dietary supplement fights disease or enhances disease-fighting functions of the body is a disease claim

• Context and specificity are important

• *Compare* “supports the body's ability to resist infection” and “supports the body's antiviral capabilities” *with* “supports the immune system”
Treat, Prevent or Mitigate Adverse Events Associated with a Disease Therapy

• A claim that a product will affect adverse events associated with a therapy for disease is a disease claim if the adverse event is itself a disease

• **Compare** “to maintain the intestinal flora in people on antibiotics” *with* “helps maintain intestinal flora”
Otherwise Suggests Effect on a Disease or Diseases

- All other implied disease claims
- Wording and/or context of particular claim on the product’s label or labeling makes it an implied disease claim
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