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FDLI
Introduction to Food Law and Regulation

Dietary Supplements

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Dietary Supplements

Background / History

Pre 1994

Post 1994

Dietary Supplement Health & Education Act (DSHEA)

Dietary Supplement Health and Education Act

- October 1994: the Dietary Supplement Health and Education Act (DSHEA) was signed into law by President Clinton
- DSHEA amended the Food, Drug and Cosmetic Act (FDCA), creating a new regulatory framework for the safety and labeling of dietary supplements, distinct from conventional foods and drugs
  - Defined dietary supplement and dietary ingredient
  - Removed dietary supplements from the “food additive” definition
  - Permitted structure/function claims for dietary supplements
  - Introduced safety standards specific to dietary supplements and ingredients
  - Established certain labeling requirements for dietary supplements
- Under DSHEA, the manufacturer/distributor is responsible for ensuring that a dietary supplement is safe before it is marketed
  - Must also ensure that product label information is truthful and not misleading

Definition of a Dietary Supplement

The term ‘‘dietary supplement’’—

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E); (21 U.S.C. § 321(ff)(1))

Definition of a Dietary Supplement

- Not represented as a conventional food (21 U.S.C. § 321(ff)(2)(B))
- Not represented as sole item of a meal or the diet (21 U.S.C. § 321(ff)(2)(B))
- Labeled as a dietary supplement (21 U.S.C. § 321(ff)(2)(C))
- Must be ingested (21 U.S.C. § 321(ff)(2)(A))
- Approved new drugs and biological products? "Race to Market" provisions
  - A dietary supplement does include an article:
    - that is approved as a new drug or licensed as a biologic and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food *unless* the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under § 342(f) (21 U.S.C. § 321(ff)(3)(A))
  - A dietary supplement does not include an article:
    - that is approved as a new drug, certified as an antibiotic, or licensed as a biologic, or
    - authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

      which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter. (21 U.S.C. § 321(ff)(3)(B))

Dietary Supplements

Identity and Specifications of a DS / DI

Chemical Modification / Alteration of a DI

“Marketing” of a DI / DS

“In a Food” vs “As a Food”

Dietary Supplements
New Dietary Ingredients (NDIs)

A new dietary ingredient (NDI) is simply a dietary ingredient that was not marketed in the United States before October 15, 1994—the effective date of DSHEA.

A dietary supplement containing an NDI is adulterated unless either of two requirements is met:

- dietary ingredients that have been present in the food supply as articles used for food… in a form in which the food has not been chemically altered; or
- there is a history of use…and, at least 75 days before…NDIN

Dietary Supplements
"Old Dietary Ingredients" (ODIs)

ODI or "Grandfathered Ingredients"

No true definition in Act, just not NDIs.

Marketed in U.S. pre-DSHEA.

Identity *really* matters.

No premarket notification

Still need basis for safety prior to going to market.

Dietary Supplements
Good Manufacturing Practices (GMPs)

21 C.F.R. Part 111 – “Current Good Manufacturing Practices in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.”

Minimum standards, broader applications than simply “manufacturing.”

Fractionated (often) process of bring DS to market; many can be responsible, distributor is ultimately accountable.

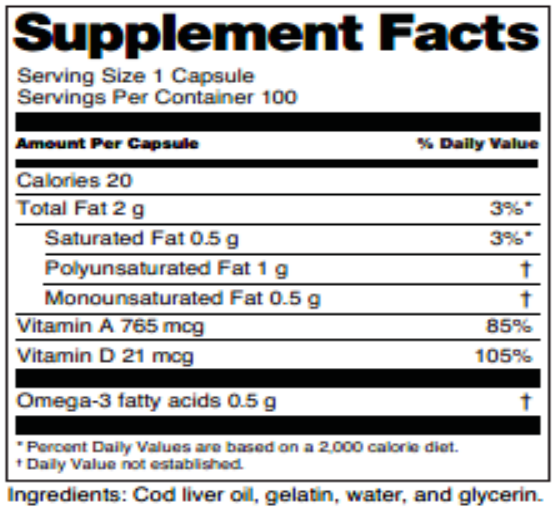
Systematic approach to ensure safety / integrity of DS.

Dietary Supplements Label

Principle Display Panel (PDP)

Information Display Panel (IDP)

Supplement Facts label



Supplement Facts

Serving Size 1 Capsule
Servings Per Container 100

Amount Per Capsule	% Daily Value
Calories 20	
Total Fat 2 g	3%*
Saturated Fat 0.5 g	3%*
Polyunsaturated Fat 1 g	†
Monounsaturated Fat 0.5 g	†
Vitamin A 765 mcg	85%
Vitamin D 21 mcg	105%
Omega-3 fatty acids 0.5 g	†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Ingredients: Cod liver oil, gelatin, water, and glycerin.

Along with any information required by applicable provisions of labeling requirements found elsewhere in the regulations and the separate requirements of DSHEA, information that must be included on the label of a dietary supplement includes: a statement of identity; the net quantity of the contents; nutrition labeling; an ingredient list; information about any major food allergens; and the name and place of business of the manufacturer, packer, or distributor.

Dietary Supplements
S/F Claims Intended Use Disease Claims

Like all food, the labels and labeling of dietary supplements can include, if properly supported, nutrient content claims and health claims. DSHEA, however, laid out the basis for how the labels and labeling of dietary supplements could include what are known as structure/function (S/F) claims.

Intended Use: FDA will look to statements and information on the label and labeling of an FDA-regulated product to establish the objective intent of the party responsible for placing the product into commerce.

Disease Claim: a claim for the prevention, treatment, cure, or mitigation of a disease and a disease is defined as “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 dysfunction.”

Dietary Supplements

Product Complaints

Adverse Events

Registration

Inspections

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