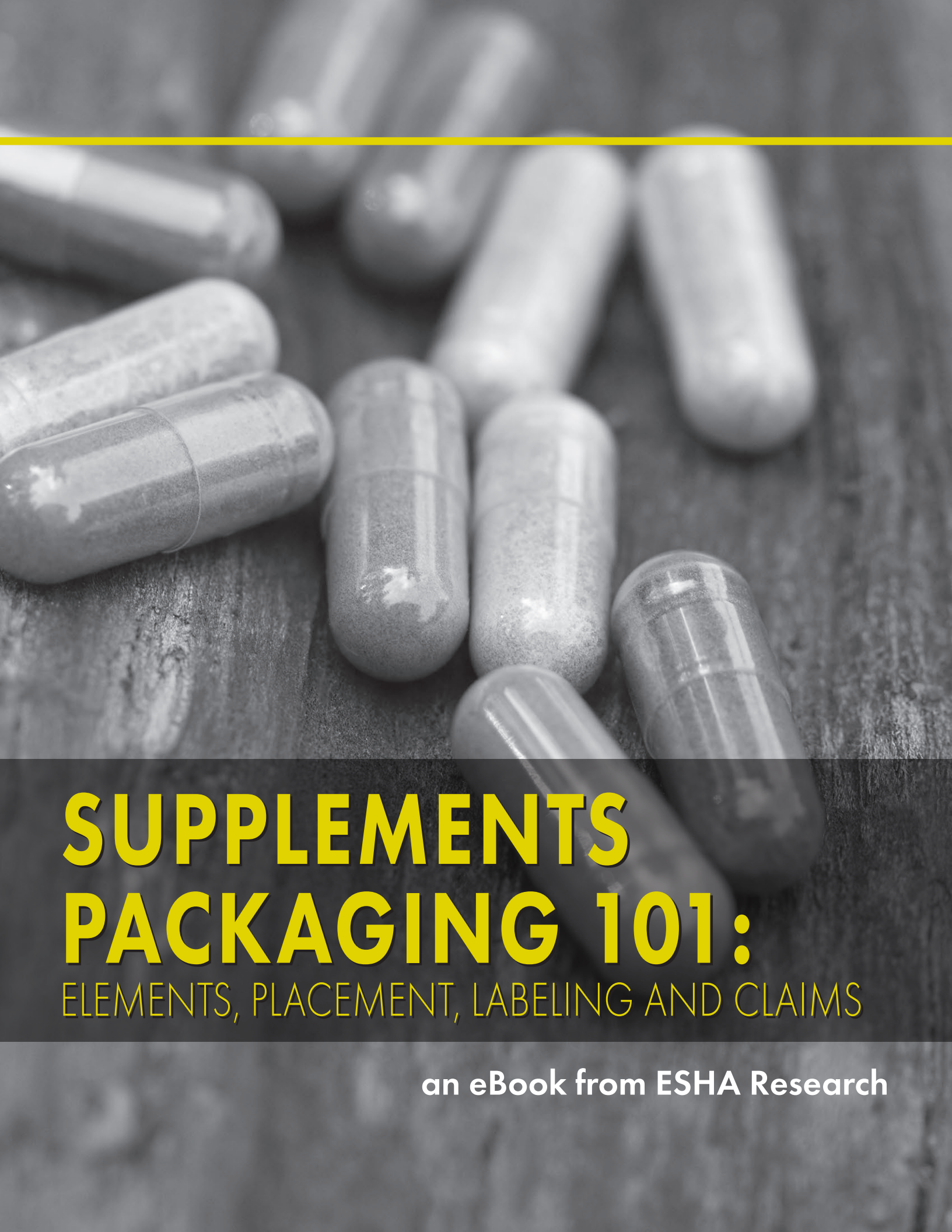

SUPPLEMENTS PACKAGING 101:

ELEMENTS, PLACEMENT, LABELING AND CLAIMS

an eBook from ESHA Research

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Introduction.

In 1994, Congress passed the Dietary Supplement Health and Education Act (DSHEA) to (1) define what a supplement is (2) to set regulations for labeling and packaging and (3) change the scope of the FDA to include removal of unsafe or misbranded products from the market and to establish safe manufacturing practices.

This ebook will briefly cover the first two topics to help guide you through the regulations and requirements for Supplement Facts labeling compliance.

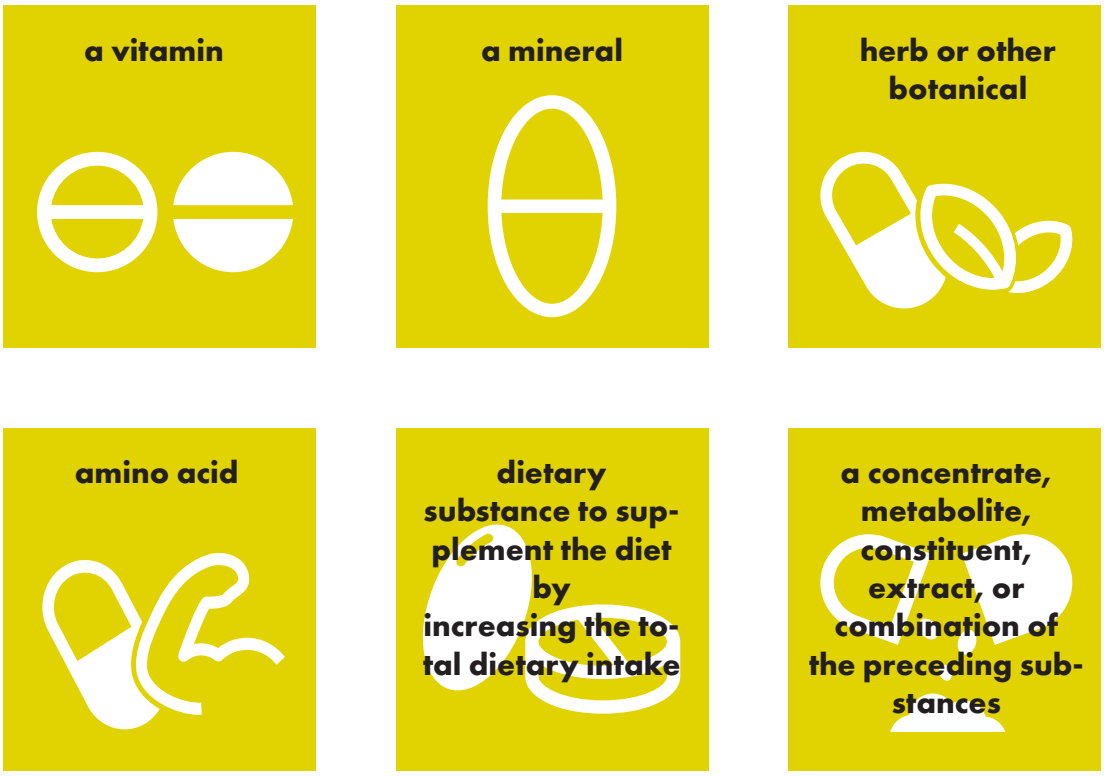
Please remember, while we can provide you with basic guidelines for compliance, you are ultimately responsible for understanding and applying the regulations.

Definition.

WHAT IS A DIETARY SUPPLEMENT?

In general, dietary supplements are products that contain one or more "dietary ingredients," are intended to supplement the diet, and are not to be represented as conventional foods or as a sole item of a meal. In addition, they are typically ingested as gelcaps, softgels, capsules, tablets, liquids, or powders.

More specifically, the Federal Food, Drug, and Cosmetic Act defines a (non-tobacco) dietary ingredient as:



Packaging Basics.

WHAT IS REQUIRED?

FDA-regulated supplement packages must contain the following components:

- Statement of Identity
- Net Quantity Statement
- Name and address of manufacturer, packer, or distributor
- Supplement Labeling

In addition, when present or necessary, packaging must also show:

- Ingredient Statement
- Allergen Statement
- Nutrient Content Claim(s)

All required items must be placed either on the Principal Display Area (PDP) or the Information Panel. The regulations dictate each component's placement, type size requirements, and more.

Packaging Basics.

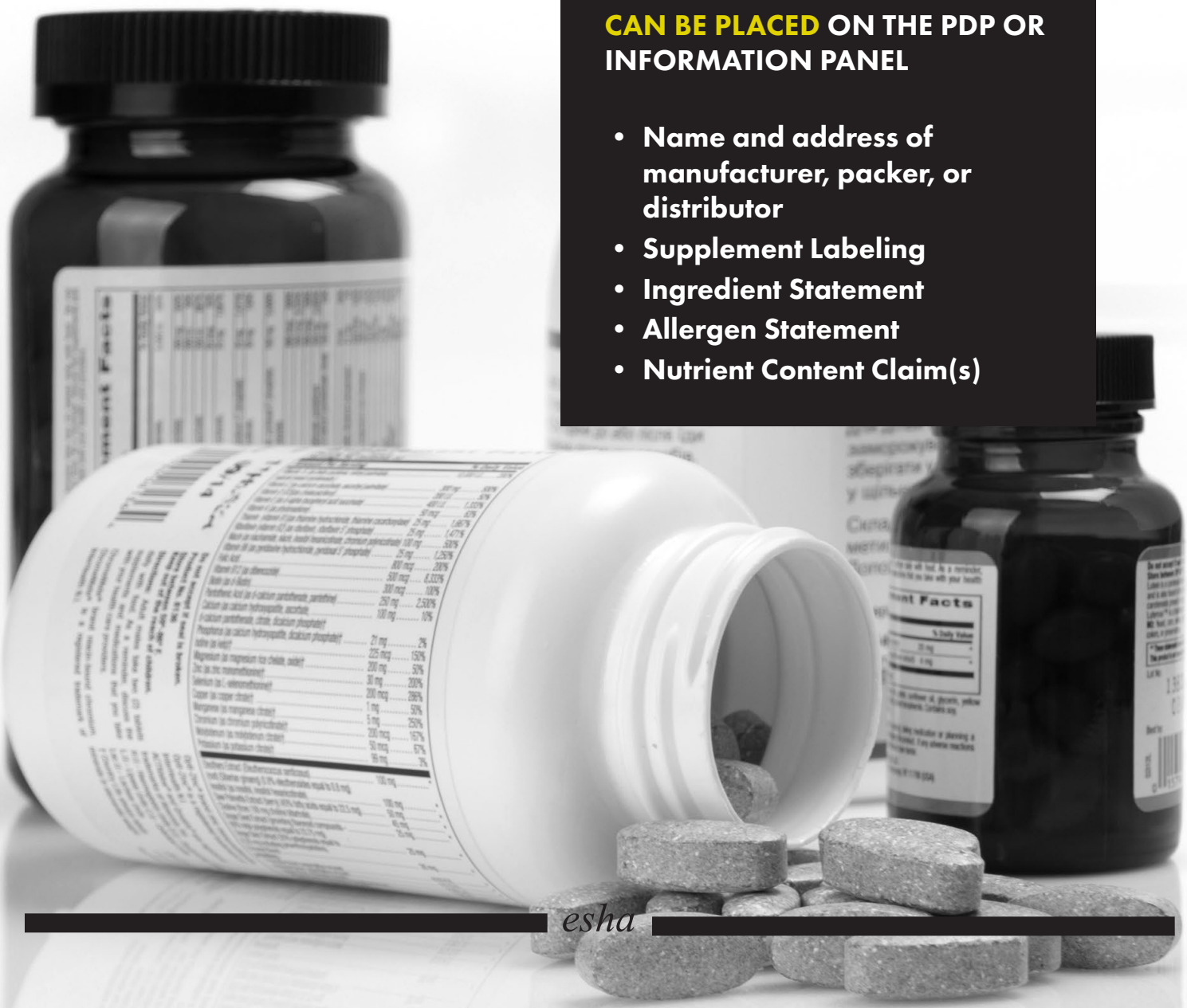
PLACEMENT

REQUIRED ON THE PDP (PRINCIPAL DISPLAY PANEL)

- Statement of Identity
- Net Quantity Statement

CAN BE PLACED ON THE PDP OR INFORMATION PANEL

- Name and address of manufacturer, packer, or distributor
- Supplement Labeling
- Ingredient Statement
- Allergen Statement
- Nutrient Content Claim(s)



Packaging Areas Defined.

PDP

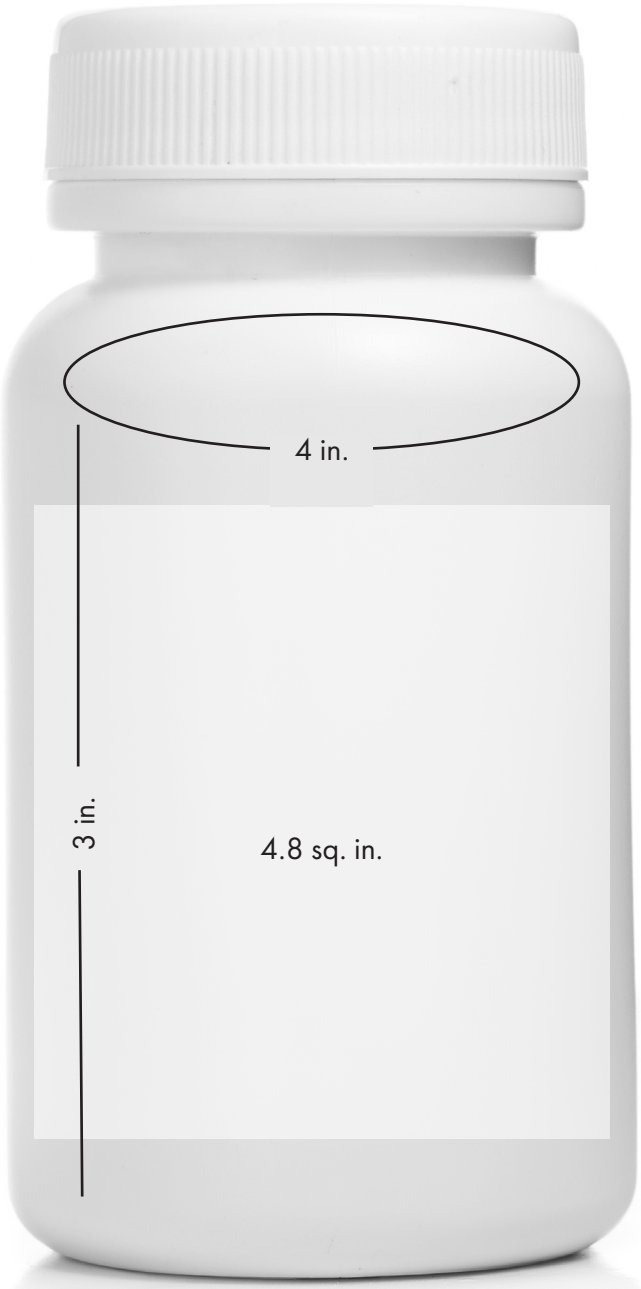
(Principal Display Panel)

The Principal Display Panel is the area most likely to be seen by a buyer at the time of purchase, which in most cases is the front of the supplement bottle. There may be other suitable areas, called alternate PDPs, but we will focus on the primary PDP here. For a cylindrical container like a supplement bottle, the PDP area is 40 percent of the area, which is found by multiplying the height times the circumference.

Example:
A bottle is 3 inches in height and the circumference is 4 inches around.

- 3 x 4 =12 square inches
- 40% x 12 = 4.8 square inches

In this example, the PDP is a 4.8 square-inch area.



INFORMATION PANEL

The information panel is the panel or area (if, say, the package is a bottle) immediately to the right of the PDP, as displayed to the consumer.

Package Elements.

Required: Always.

Location: PDP.

Format: Bold type, same size or larger than most prominent printed element, parallel to the base.

NOTE
The Statement of Identity is not the brand.

STATEMENT OF IDENTITY

The statement of identity is the name of the supplement and can be shown in one of the following ways:

- The common or usual name of the dietary ingredient, followed or preceded by the term "dietary supplement."

Vitamin D
DIETARY SUPPLEMENT

DIETARY SUPPLEMENT
Vit. D

- The common or usual name of the dietary ingredient plus the word "supplement."

CALCIUM SUPPLEMENT

- Or, if there is no common or usual name and the nature of the supplement is not obvious, the statement of identity must be an appropriately descriptive term.

Herbal Supplement with Vitamins

Package Elements.

Required: Always.

Location: Bottom 30% of PDP.

Format: Prominent, conspicuous, and easy to read. Type size depends on package size.

(See bullet points and chart below.)

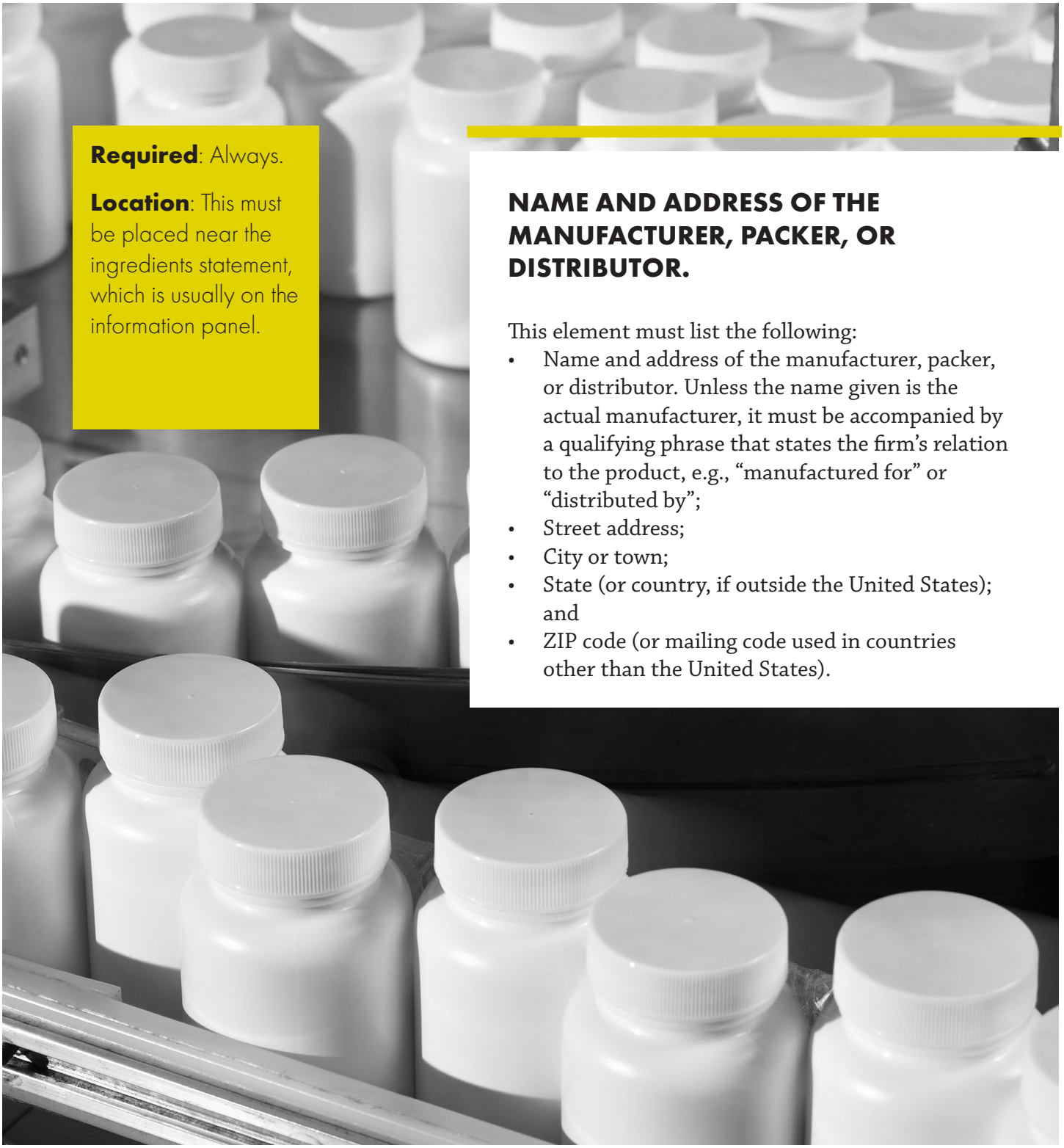
NET QUANTITY OF CONTENTS, OR AMOUNT OF PRODUCT

The net quantity statement tells consumers how much of the supplement is in the container or package. This is either the total number of capsules/pills or the net fluid amount, and is listed by weight, measure, numerical count (e.g. 100 tablets), or combination thereof.

- The smallest type size permitted for the net quantity of contents statement is based on the size of the principal display panel.
- If the principal display panel is 5 square inches or less, the requirement for placement within the bottom 30 percent does not apply when the declaration of net quantity of contents meets the other requirements of 21 CFR 101.105(f).

Minimum Type Size	***Area of PDP***
1/16 in. (4.5 point)	5 sq. in.
1/8 in. (9 point)	More than 5 sq. in. but not more than 25 sq. in.
3/16 in. (13.5 point)	More than 25 sq. in. but not more than 100 sq. in.
1/4 in. (18 point)	More than 100 sq. in. but not more than 400 sq. in.
1/2 in. (36 point)	Over 400 sq. in.

Package Elements.



Required: Always.

Location: This must be placed near the ingredients statement, which is usually on the information panel.

NAME AND ADDRESS OF THE MANUFACTURER, PACKER, OR DISTRIBUTOR.

This element must list the following:

- Name and address of the manufacturer, packer, or distributor. Unless the name given is the actual manufacturer, it must be accompanied by a qualifying phrase that states the firm's relation to the product, e.g., "manufactured for" or "distributed by";
- Street address;
- City or town;
- State (or country, if outside the United States); and
- ZIP code (or mailing code used in countries other than the United States).

Supplement Facts Label.

The Supplement Facts label is rigorously regulated, which is why this eBook devotes an entire section to it.

PLACEMENT

Required: Always.

Location: Usually on the information panel, alongside or near the ingredients list and the manufacturer's information.

Supplement Facts

Serving Size 1 Tablet
Servings Per Container 60

Amount Per Serving		% Daily Value
Vitamin A	900 mcg	100%
Vitamin C	90 mg	100%
Vitamin D	20 mcg (800 IU)	100%
Vitamin E	15 mg	100%
Thiamin	1.2 mg	100%
Riboflavin	1.3 mg	100%
Niacin	16 mg	100%
Vitamin B6	1.7 mg	100%
Folate	680 mcg DFE (400 mcg folic acid)	170%
Vitamin B12	2.4 mcg	100%
Biotin	30 mcg	100%
Pantothenic Acid	5 mg	100%
Choline	550 mg	100%
Fluoride	20 mg	†

Supplement Facts

Serving Size 2 Tablet
Servings Per Container 50

Amount Per Serving		% Daily Value
Calcium (as Calcium Citrate, Calcium Malate)	500 mg	38%
Magnesium (as Magnesium Citrate, Magnesium Oxide)	250 mg	60%

Supplement Facts Serving Size 1 Capsule, Servings 50, Amount Per Serving: Rose Hip Extract (flower) 50 mg, Echinacea Extract (whole) 50 mg.

Supplement Facts

Serving Size 2 Tablet
Servings Per Container 50

	Amount Per Serving	%DV
Vitamin C (as Ascorbic Acid)	500 mg	556%
Zinc (as Zinc Amino Acid Chelate)	20 mg	182%
Copper (as Copper Amino Acid Chelate)	1.2 mg	133%
Herbal Blend	100 mg	†
Rose Hips (flower)	50 mg	†
Echinacea Purpurea Extract (whole herb)	50 mg	†

† Daily Value (DV) not established

Supplement Facts Label.

DETERMINING SUPPLEMENT FACTS LABEL STYLE.

The rule of thumb is that you must use a standard Supplement Facts label on packages with 12 sq. inches or larger. Most supplement bottles meet this minimum size requirement.

Supplement Facts

Serving Size 1 Tablet
Servings Per Container 60

Amount Per Serving		% Daily Value
Vitamin A	900 mcg	100%
Vitamin C	90 mg	100%
Vitamin D	20 mcg (800 IU)	100%
Vitamin E	15 mg	100%
Thiamin	1.2 mg	100%
Riboflavin	1.3 mg	100%
Niacin	16 mg	100%
Vitamin B6	1.7 mg	100%
Folate	680 mcg DFE (400 mcg folic acid)	170%
Vitamin B12	2.4 mcg	100%
Biotin	30 mcg	100%
Pantothenic Acid	5 mg	100%
Choline	550 mg	100%
Fluoride	20 mg	†

† Daily Value not established

If, however, your package is smaller than 12 sq. inches, you may use the linear format.

Supplement Facts Serving Size 1 Capsule, Servings 50, Amount Per Serving: Rose Hip Extract (flower) 50 mg, Echinacea Extract (whole) 50 mg.

Type size requirements for package sizes greater than 40 square inches

- Most text within the Supplement Facts label (with the exception of the title, headings, and footnotes) should be in uniform type size no smaller than 8 point.
- Type size no smaller than 6 point may be used for column headings (e.g., “Amount Per Serving” and “% Daily Value”) and for footnotes (e.g., “Percent Daily Values are based on a 2,000 calorie diet”).

For type size requirements for small and intermediate-size packages refer to CFR101.36i2

Supplement Facts Label.

REQUIRED ELEMENTS.

SERVING SIZE

The serving size of a dietary supplement equals the maximum amount recommended on the label for consumption per eating occasion. For example, if the directions on your label say to take 1-3 tablets with breakfast, the serving size would be 3 tablets.

In the absence of recommendations, the serving size should be listed using a term that is appropriate for the form of the supplement.

Examples:
_ tablet(s)
_ capsules(s)
_ packet(s)
_ tsp(s)
_ g

Required: Always.

Location: The subheading "Serving Size" should be placed under the "Supplement Facts" heading.

Alignment: Serving Size should be aligned on the left side of the label.

Font: 8-point minimum.

SERVINGS PER CONTAINER

This is the number of units (or servings) of the supplement (based on the serving size) that the package contains.

Example:
Serving Size 2 Tablets
Servings per Container 50

Required: Yes, unless it's stated in the net quantity of contents declaration.

Location: Servings Per Container should be placed under the Serving Size subheading.

Alignment: On the left side of the label.

Font: 8-point minimum.

Supplement Facts Label.

NUTRIENTS

Nutrients Above the Line

Nutrients listed *above* the line on Supplement Facts labels *are governed by NLEA rules* and are either classified as mandatory or voluntary. Mandatory nutrients must be listed on the label if they are present in a significant amount. Listing voluntary nutrients is optional unless a claim is being made. Most of these nutrients will have a % Daily Value.

Supplement Facts

Serving Size 2 Tablet
Servings Per Container 50

	Amount Per Serving	%DV
Vitamin C (as Ascorbic Acid)	500 mg	556%
Zinc (as Zinc Amino Acid Chelate)	20 mg	182%
Copper (as Copper Amino Acid Chelate)	1.2 mg	133%
Herbal Blend	100 mg	†
Rose Hips (flower)	50 mg	†
Echinacea Purpurea Extract (whole herb)	50 mg	†

† Daily Value (DV) not established

Nutrients Below the Line

Nutrients listed below the line are defined as Other Dietary Ingredients, and include botanicals, special blends, and the like. These must appear on the Supplement Facts label if they are present in a significant amount (greater than zero). They will not have an associated %DV.

NOTE: When you make a claim, or add a nutrient to a product for proposes of supplementation, you must list that nutrient (even if it is considered a 'voluntary' nutrient or has an insignificant amount).

Example: If you claim "High in Vitamin C," you must have Vitamin C listed on the Supplement Facts label.

Supplement Facts Label.

The list of nutrients on the Supplement Facts label are ordered differently than they are on the Nutrition Facts label.

This chart shows the order in which the nutrients must be listed, whether they are mandatory or voluntary in significant amounts, and what the daily value is for adults and children > 4 years.

Label Nutrient	*Mandatory/Voluntary*	*Daily Value*
Calories	M	-
Calories from Saturated Fat	V	-
Total Fat	M	78 gm
Saturated Fat	M	20 gm
Trans Fat	M	-
Polyunsaturated Fat	V	-
Monounsaturated Fat	V	-
Cholesterol	M	300 mg
Total Carbohydrate	M	275 gm
Dietary Fiber	M	28 gm
Soluble Fiber	V	-
Insoluble Fiber	V	-
Total Sugars	M	-
Added Sugars	M	50 gm
Sugar Alcohol	V	-
Protein	M	50 gm
Vitamin A	V	900 mcg RAE
Vitamin C	V	90 mg
Vitamin D	M	20 mcg
Vitamin E	V	15 mg a-tocopherol
Vitamin K	V	120 mcg
Thiamin	V	1.2 mg
Riboflavin	V	1.3 mg
Niacin	V	16 mg NE
Vitamin B6	V	1.7 mg
Folate/Folic Acid	V	400 mcg DFE
Vitamin B12	V	2.4 mcg
Biotin	V	30 mcg
Pantothenic Acid	V	5 mg
Choline	V	550 mg
Calcium	M	1300 mg
Iron	M	18 mg
Phosphorus	V	1250 mg
Iodine	V	150 mcg
Magnesium	V	420 mg
Zinc	V	11 mg
Selenium	V	55 mcg
Copper	V	0.9 mg
Manganese	V	2.3 mg
Chromium	V	35 mcg
Molybdenum	V	45 mcg
Chloride	V	2300 mg
Sodium	M	2300 mg
Potassium	M	4700 mg
Fluoride	V	-

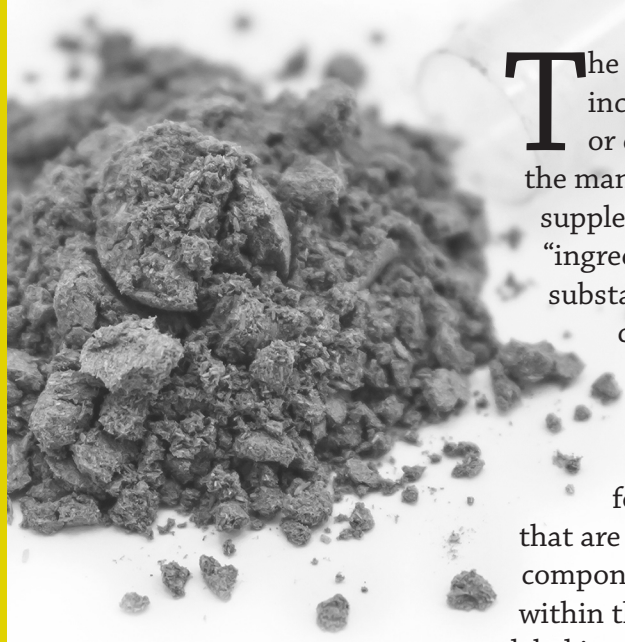
Supplement Facts Label.

Required:
Sometimes. Specifically when the ingredients are not listed on the Supplement Facts label itself.

Location:
In general, below or alongside the Supplement Facts label.

Format:
In a type size that's at least 1/16" tall and easy to read.

"Ingredients" must precede the ingredient list. If some ingredients are identified within the Supplement Facts label, use "Other Ingredients."



INGREDIENT STATEMENT

The ingredient statement includes the ingredients or compounds used in the manufacture of a dietary supplement. The term "ingredient" also refers to substances such as binders, colors, excipients, fillers, flavors, and sweeteners.

The FDA allows for ingredients that are sources of dietary components to be listed within the Supplement Facts label itself.

Example: "Calcium (as calcium carbonate)" would appear in the Supplement Facts label.

When ingredients are listed in this way, they do not have to be listed again in the ingredient statement. As a result, not all supplement labels will have ingredient statements. Many times, the ingredient statement will show only fillers, excipients, or other inactive ingredients.

Required:
When allergens are present.

Location:
In the ingredients list or immediately after.

Supplement Facts Label.

ALLERGEN STATEMENT

Supplement manufacturers are required to declare, in plain language, the presence of any major food allergens on the product packaging

The law defines a major food allergen to mean any one of the following nine foods or food groups (or an ingredient that contains their proteins):

- milk
- egg
- fish
- crustacean shellfish
- tree nuts
- wheat
- peanuts
- soybeans
- sesame

The allergen may either appear in parentheses after the name of the ingredient in the ingredients list OR immediately after the list (or adjacent to) in a "contains" statement.

Examples:

Lecithin (soy), whey (milk) … or
Contains: Soy and milk.

In the case of possible cross-contamination, many manufacturers voluntarily include a statement that says, for example, "may contain [allergen]" or "produced in a facility that also uses [allergen]". The FDA warns that this is not a substitute for safe manufacturing practices.

Claims.

As mentioned in the introduction, packing and advertising claims are heavily regulated by the FDA.

There are, essentially, three types of claims:

- Nutrient content claims
- Health claims
- Structure/function claims

NUTRIENT CONTENT CLAIMS

A nutrient content claim is a declaration or characterization of the amount or level of a nutrient in a product (e.g. "good source of" or "high in").

In general, nutrient content claims are based on the percent daily value per RACC. For example, the statement "High in calcium" can be made if there is 20% or more of the DV per RACC. Whereas the statement "High potency iron" can only be made if there is 100% or more of the RDI per RACC.

There is another category of nutrient content claims for dietary supplements, which is referred to as a percentage claim. A *percentage claim* is a statement that characterizes the percentage level of a nutrient or dietary ingredient in a dietary supplement. These can be used for nutrients for which there is no established DV or RDI. A percentage statement must include the dietary ingredient amount per serving next to the percent declaration. For example:

40% omega-3 fatty acids (this is the percentage statement), 10 mg per capsule (this is the nutrient per serving amount).

You can also us a comparative percentage claim:

Twice the omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg)

The electronic Code of Federal Regulations online (21 CFR 101.13) outlines the specific requirements for making such statements.

Claims.

HEALTH CLAIMS

Health claims describe a relationship between a food substance (a food, food component, or dietary supplement ingredient), and reduced risk of a disease or health-related condition. For example:

"Calcium may reduce the risk of osteoporosis."

There are two types of health claims allowed on dietary supplements: NLEA Authorized Health Claims and Qualified Health Claims.

NLEA Authorized Health Claims are reviewed and approved by the FDA using the Significant Scientific Agreement (SSA) standard. The FDA uses the SSA to determine if there is enough supporting evidence and scientific agreement among experts qualified to evaluate such claims.

Refer to the Code of Federal Regulations to see what health claims have already been authorized.

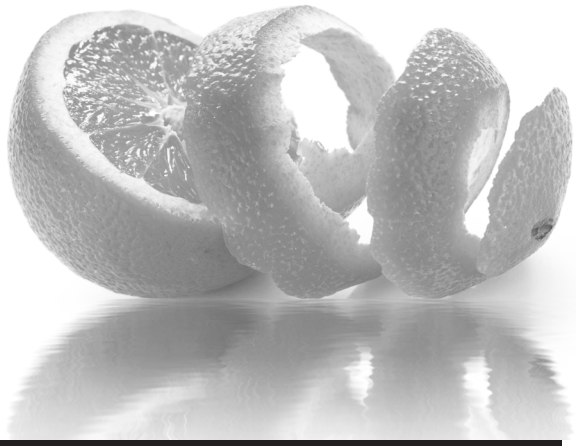
- Authorized Health Claims are listed in the 21 CFR 101.72 through 101.83
- Unauthorized Health Claims are listed in the 21 CFR 101.71
- Petitions for health claim instructions are listed in the 21 CFR 101.70

Qualified health claims are used when there is supportive scientific evidence for a relationship between a dietary ingredient and a reduced risk of a health-related condition. Because qualified health claims do not meet the "significant scientific agreement" standard required for an authorized health claim, qualified health claims must be accompanied by a disclaimer.

Example: Qualified Health Claim for Vitamin C

"Vitamin C may reduce the risk of colon cancer. The scientific evidence supporting this claim is persuasive, but not conclusive."

These claims require approval by the FDA prior to going to market. Before making a health claim, do your research. An extensive explanation of health claims is in the CFR (21 CFR 101.14).



Claims.

STRUCTURE/FUNCTION CLAIMS

Structure/function claims may describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body. For example:

"Calcium maintains healthy bones."

Structure/function claims may not describe a relationship or intent to affect a disease.

To use a structure/function claim, you must have substantiating documentation. Additionally, you must notify the FDA that you are using the claim no later than 30 days after first marketing the product with the associated claim. Unlike health claims, structure/function claims do not require approval, but you must include this disclaimer:

> *"This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."*

Claims.

If the label or labeling (including advertising material, websites, and social media pages) of a product marketed as a dietary supplement bears a disease claim and does not qualify as an authorized health claim, the product will be subject to regulation as a drug. In such case, the supplement manufacturer will receive a warning letter from the FDA similar to this one:

> *This is to advise you that the Food and Drug Administration (FDA) has reviewed your websites at the Internet address [redacted] in March 2017 and has determined that you take orders there for the product [redacted]. The claims on your websites establish that your product is a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)] because it is intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering this product for introduction into interstate commerce for such uses violates the Act. You can find the Act and FDA regulations through links on FDA's home page at http://www.fda.gov.*
>
> *Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201(p) of the Act [21 U.S.C. 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. 331(d),355(a)]. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.*

EXAMPLES OF SUPPLEMENTS CLAIMS:

- **Helps improve your mood**
- **Adequate intake of calcium may reduce the risk of osteoporosis**
- **Supports the immune system**

EXAMPLES OF DRUG CLAIMS:

- **Reduces depression**
- **Treats heart disease**
- **Fights cancer**
- **Reduces inflammation**
- **Painkiller**

Please keep in mind that there are many nuances and particularities with labeling supplements and botanicals. This eBook is meant to be an overview of the regulations.

FOR FURTHER INFORMATION PLEASE REFER TO THE CODE OF FEDERAL REGULATIONS AT WWW.ECFR.GOV. USE THE DROP-DOWN MENU TO SELECT TITLE 21 AND CLICK ON

The Code of Federal Regulations
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=bb7a4e027421ad6e-a76897023839b905&mc=true&n=sp21.2.101.a&r=SUBPART&ty=HTML

Guidance for Industry: A Dietary Supplement Labeling Guide
https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm2006823.htm

RACC Tables
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?-fr=101.12

Label Claims for Conventional Foods and Dietary Supplements
https://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm111447.htm

Dietary Supplement Health And Education Act of 1994
https://health.gov/dietsupp/ch1.htm

ESHA Research has been the leading provider of nutrition databases, food and supplement labeling, and nutrition analysis software solutions for more than 35 years. Our team of consultants are knowledgeable in nutrition, labeling, and regulatory compliance, ensuring your unique needs are met.

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