



# Dietary Supplement Labeling

**Siobhan Gallagher Taylor**

Dietary Supplement National Expert

Office of Global Specialty Human Food Inspectorate

Office of Inspections and Investigations

U.S. Food & Drug Administration

# What is a Dietary Supplement?



# Definition of Dietary Supplements

## Food Drug & Cosmetic Act – 201(ff)

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)

# Definition of Dietary Supplements

## Food Drug & Cosmetic Act – 201(ff)

The term “dietary supplement” –

- (2) means a product that:
  - (A)(i) is **intended for ingestion** in a form described in section 350(c)(1)(B)(i) of this title; or
  - (ii) complies with section 350(c)(1)(B)(ii) of this title;
  - (B) is **not represented for use as a conventional food** or as a sole item of a meal or the diet; and
  - (C) **is labeled as a dietary supplement**

# Definition of Dietary Supplements

## Food Drug & Cosmetic Act – 201(ff)

The term “dietary supplement” –

- (2) means a product that:
  - (B) **does not include-**
  - (i) **an article that is approved as a new drug** under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42, or
  - (ii) **an article 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.



# Simplified Definition of Dietary Supplements

## **A dietary supplement is a product:**

- Taken by mouth in a form that can be ingested (i.e. powder, capsule, tablet, liquid, gummy, softgel, etc.)
  - Containing a “dietary ingredient”
- Not represented for use as a conventional food or meal replacement
  - Does not include approved or investigational drugs
    - And is labeled as a dietary supplement

# Is It A Supplement?

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# Is It A Supplement?

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**It  
Depends**





# Is It A Supplement?



**Sijgood**

**Supplement Facts**

Serving Size: 2 Gummies  
Servings per Container: 30

Amount Per Serving	% Daily Value*
Calories	7.5
Total Carbohydrate	2g 1%
Total Sugars	1g 2%
Vitamin D3 (as Cholecalciferol)	10mcg 50%
Calcium (from oyster shell)	500mg 38%
Potassium (as Potassium Gluconate)	89mg 2%
Vitamin B6 (as Pyridoxine Hydrochloride)	100mg 5682%
Providing Elemental Magnesium: Magnesium Glycinate ADVANCED COMPLEX 500mg (as 400mg Magnesium Glycinate and 200mg Magnesium L-Threonate)	70.8mg 17%
Coenzyme Q10	100mg *
Black Pepper	100mg *

\* Daily Value (DV) not established. \* Percent Daily Values are based on a 2000 calorie diet.

**Sijgood**  
**MAGNESIUM GUMMIES**  
60 STRAWBERRY FLAVORED GUMMIES  
DIETARY SUPPLEMENT

100%  
Certified Vegan

Non-GMO

Gluten Free

Gelatin Free

Organic Ingredients



**Nutrition Facts**

About 3.5 servings per container  
**Serving size 13 Pieces (30g)**

Amount per serving	% Daily Value*
<b>Calories</b> 100	
<b>Total Fat</b> 0g	<b>0%</b>
<b>Sodium</b> 5mg	<b>0%</b>
<b>Total Carbohydrate</b> 23g	<b>8%</b>
Total Sugars 14g	
Includes 14g Added Sugars	<b>28%</b>
<b>Protein</b> 2g	

Not a significant source of saturated fat, trans fat, cholesterol, dietary fiber, vitamin D, calcium, iron and potassium.

\*The % Daily Value is shown here to help you know how much a serving of a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

**INGREDIENTS:** GLUCOSE SYRUP (FROM WHEAT OR CORN), SUGAR, GELATIN, DEXTROSE (FROM WHEAT OR CORN), CONTAINS LESS THAN 2% OF CITRIC ACID, ARTIFICIAL AND NATURAL FLAVORS, PALM OIL, PALM KERNEL OIL, CAPSAICIN WAX, WHITE BEESWAX, YELLOW BEESWAX, YELLOW'S, RED 40, BLUE 1.

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# Is It A Supplement?

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# Is It A Supplement?



**It  
Depends**







# Is It A Supplement?

**DOUBLE RICH CHOCOLATE** ARTIFICIALLY FLAVORED

**Nutrition Facts**  
74 servings per container  
**Serving size 30.4g (About 1 Scoop)**

Amount per serving	Calories	% Daily Value*
<b>Total Fat</b> 1.5g	<b>120</b>	<b>2%</b>
Saturated Fat 1g		5%
<b>Cholesterol</b> 55mg		<b>18%</b>
<b>Sodium</b> 130mg		<b>6%</b>
<b>Total Carbohydrate</b> 3g		<b>1%</b>
Dietary Fiber <1g		2%
<b>Protein</b> 24g		<b>48%</b>
Calcium 130mg		10%
Iron 0.7mg		4%
Potassium 200mg		4%

Not a significant source of trans fat, added sugars and vitamin D.  
\*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

**30.4 GRAMS**  
ABOUT 1 SCOOP  
WHEY PROTEIN  
POWDER

**6-8 FL OZ**  
COLD WATER,  
MILK OR OTHER  
BEVERAGE

**30 SECONDS**  
STIR, SHAKE  
OR BLEND UNTIL  
DISSOLVED

**INGREDIENTS:** Protein Blend (Whey Protein Isolate, Whey Protein Concentrate, Hydrolyzed Whey Protein), Cocoa Powder (Processed with Alkali), Sunflower and/or Soy Lecithin, Natural and Artificial Flavor, Acesulfame Potassium.

**CONTAINS: MILK AND SOY.**

**GLUTEN FREE**

**NO ARTIFICIAL GROWTH HORMONES\***

**CHOICE REGULARLY REVIEWED BANNED SUBSTANCES**

\*No significant difference has been shown between milk derived from RBST-treated and Non-RBST treated cows.

**EFM WHEY**  
quality protein from happy, grass-fed cows

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**ORGANIC BANANAS**  
real dried bananas for a potassium punch

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**ORGANIC STEVIA**  
for subtle sweetness with no added sugar

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**FAMILY OWNED • MANUFACTURED IN THE USA**

*Chris Lane D.J.*

**SUPPLEMENT FACTS**  
Serving Size 1 scoop (33g)  
Servings Per Container 27

Amount Per Serving	%DV*
Calories	120
Total Carbohydrates	6g 2%
Dietary Fiber	<1g 2%
Total Sugars	4g †
Includes Og of Added Sugar	0%
Protein	24g 48%
Calcium	140mg 11%
Phosphorus	80mg 7%
Magnesium	35mg 9%
Manganese	0.04mg 2%
Sodium	60mg 3%
Potassium	200mg 4%

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

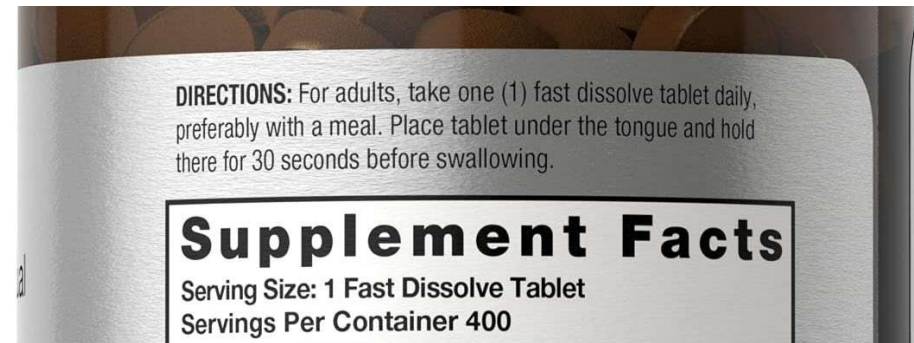
**INGREDIENTS:** Truly Grass Fed Whey Protein Isolate, Organic Freeze Dried Banana Powder, Organic Stevia, Sunflower Lecithin

**Contains: Dairy**

Manufactured for **EARTH FED MUSCLE**  
157 Germans Church Rd., Leesport, PA 19533

Do not use if seal is broken.  
After opening, close lid tightly and store in a cool, dry place.

# Is It A Supplement?



# NO

“...is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title...”

# Is It A Supplement?

- Alcohol Base
- Glycerin Base
- Water Base
- Honey Base
- Glucose Base

**It  
Depends**

“...(C) is labeled as a dietary supplement...”



# Is It A Supplement?





# Is It A Supplement?

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**Inhalable Caffeine Powder**

**NO**



# Is It A Supplement?

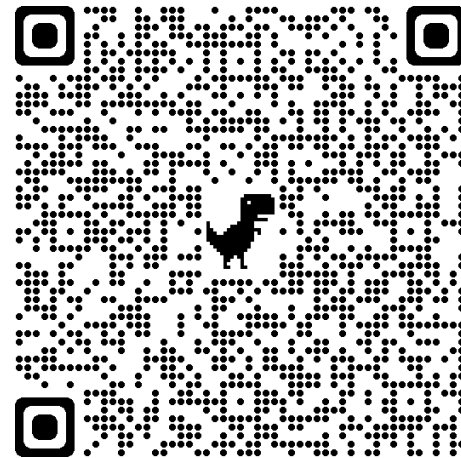
## CBD SOFTGELS



**NO**

FDA STATEMENT

**FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward**



# Is It A Supplement?



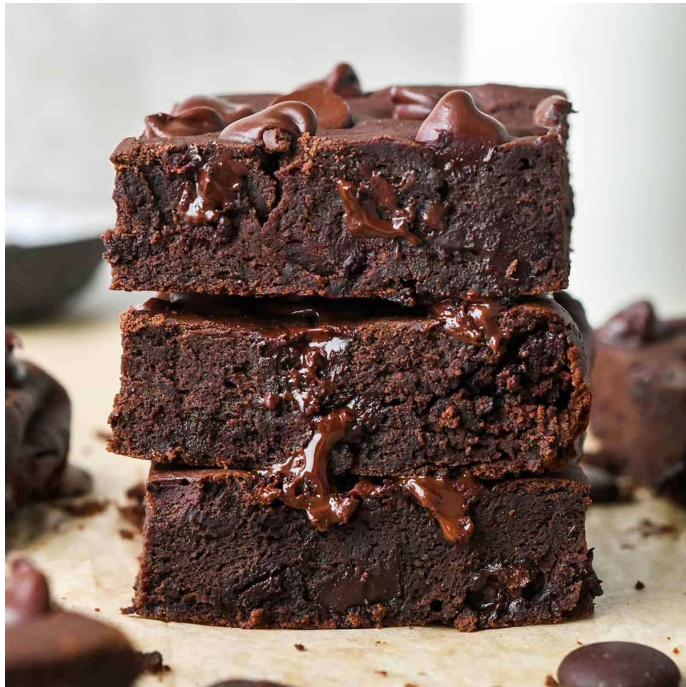
## It Depends



“...(C) is labeled as a dietary supplement...”

# Is It A Supplement?

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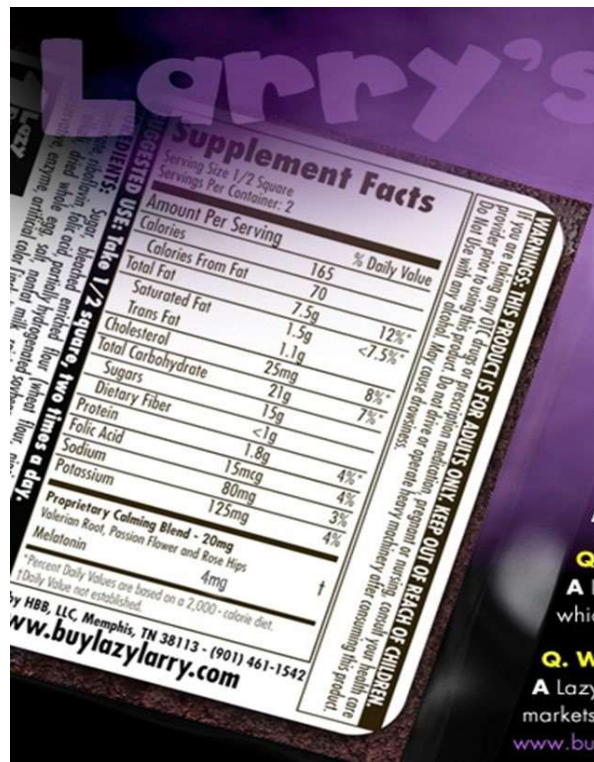


**IT  
DEPENDS**

“...is not represented for use as a conventional food...”



# Is It A Supplement?



“DIETARY SUPPLEMENT (Not for food use)”

# Is It A Supplement?

The FDA determined that this product was NOT a dietary supplement despite its labeling because:

- The product was marketed alongside other snack foods
- The name of a URL, MyLazyCakes.com, refers to a conventional food (cake)
- The product was described on the website as having the same ingredients “your mother uses to make brownies”
- The appearance and packaging of the product as a brownie
- The product was represented for use as conventional food, for example, by the use of the word “cakes” in the product name and use of the word “brownie” in the statement of identity on the package label



# Is It A Supplement?

Because the FDA determined that this product was NOT a dietary supplement, the product was deemed “unsafe”

## WHY?

Melatonin, while allowable as a dietary ingredient for use in dietary supplements, does not meet GRAS standards and cannot be used in products sold as conventional foods.





# How is a Dietary Ingredient Different From Food Ingredients?

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# What is a Dietary Ingredient?

- (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)





# DSHEA Grandfathered Ingredients

- DSHEA grandfathered ingredients are dietary supplements that were marketed in the United States before October 15, 1994.
- These ingredients do not require a pre-market New Dietary Ingredient Notification (NDIN) with the FDA.
- **Grandfathered Ingredients do not need to meet GRAS standards.**
- Industry only has two options when using dietary ingredients:
  - 1) Use a grandfathered ingredient or;
  - 2) Submit a New Dietary Ingredient Notification





# New Dietary Ingredients

## Food Drug & Cosmetic Act – 413(d)

- Manufacturers and distributors who wish to market dietary supplements that contain "new dietary ingredients" must notify the Food and Drug Administration (FDA) about these ingredients at least 75 days before being introduced or delivered for introduction into interstate commerce.
- The term "new dietary ingredient" means a dietary ingredient that was not marketed in the United States in a dietary supplement before October 15, 1994.
- **There is no authoritative list of dietary ingredients that were marketed in dietary supplements before October 15, 1994.**

# Dietary Supplement Ingredient Directory

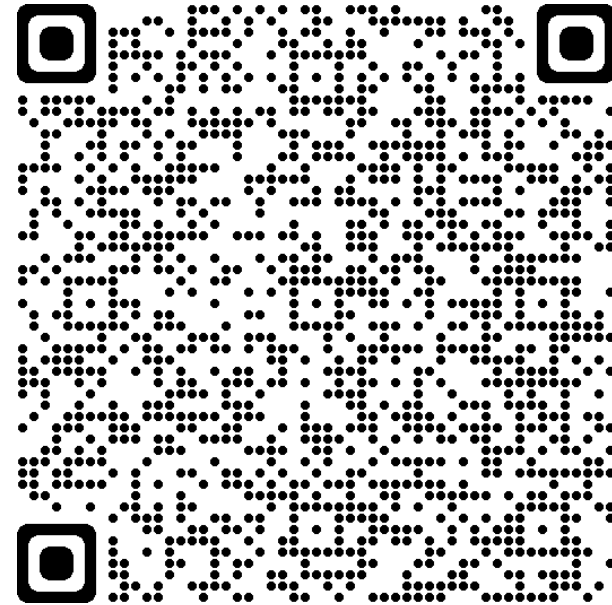
## Dietary Supplement Ingredient Directory

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Two types of ingredients may be used in dietary supplements – “dietary ingredients” and “other ingredients.” The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines a dietary ingredient as a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any dietary ingredient from the preceding categories.

Search:  Export Excel

Ingredients	Other Known Names [1]	Agency Actions/ Statements
1,4 DMAA	<ul style="list-style-type: none"> <li>1,4 dimethylpentylamine</li> <li>1,4-dimethylpentylamine</li> </ul>	<a href="#">Hi Tech Pharmaceuticals Voluntary Recall</a> (May 2021)
5-Alpha-Hydroxy-Laxogenin	<ul style="list-style-type: none"> <li>5-laxogenin</li> <li>5a-Hydroxy-Laxogenin</li> <li>(25R)-3beta,5alpha-DihydroxySpirostan-6-one</li> <li>25-R-Spirostan-5A-Diol-6-One-3-One</li> <li>25R Spirostan-5a-diol-6-one-3-one Decanoate</li> <li>25R spirostan-5a-diol-6-one-3-one undecanoate</li> </ul>	<a href="#">Constituent update and warning letters</a> (May 2022)
Acacia rigidula	<ul style="list-style-type: none"> <li>Vachellia rigidula</li> <li>Chaparro Prieto</li> <li>Blackbrush</li> </ul>	<a href="#">Acacia rigidula in Dietary Supplements</a> <a href="#">Constituent update and warning letters</a> (March 2016)
Acetaminophen	<ul style="list-style-type: none"> <li>Acetamide, N-(4-hydroxyphenyl)-</li> <li>Paracetamol</li> <li>Tylenol™</li> </ul>	<a href="#">Procter and Gamble Warning Letter</a> (October 2009)



# Structure Function Labeling

## Dietary Supplement Health and Education Act of 1994

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- DSHEA established some special regulatory requirements and procedures for structure/function claims.
- A structure/function may describe the role of a nutrient or dietary ingredient intended to affect **normal structure** or function in humans.

**For example: “*calcium builds strong bones+*  
*“X helps maintain prostate health”*”**

Final Rule: Nutrient  
Claims/Health Claims





## Dietary Supplement Health and Education Act of 1994

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- Structure/Function claims are not pre-approved by FDA.
- If a structure/function claim is included on a label, a “disclaimer” must also be present:
- 21 CFR 101.93(c-d): “Text for disclaimer. (1) Where there is one statement. The disclaimer shall be placed in accordance with paragraph (d) of this section and shall state:

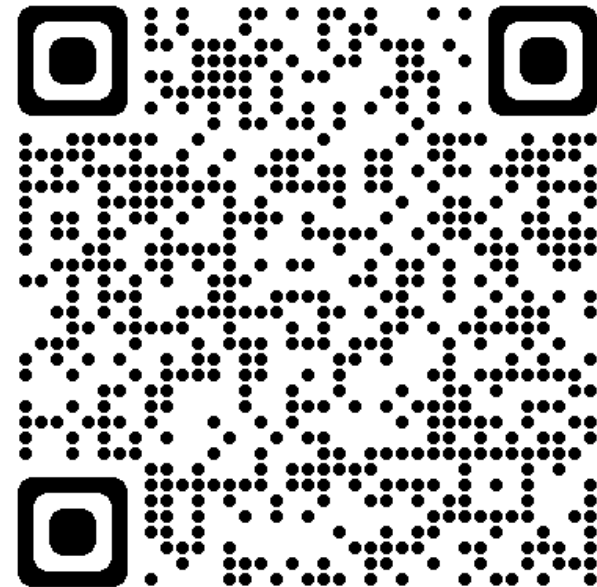
***This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”***

# Qualified Health Claims Labeling

# Qualified Health Claims

- Qualified health claims are supported by scientific evidence, but do not meet the more rigorous “significant scientific agreement” standard required for an authorized health claim.
- Food manufacturers can petition the agency to consider exercising enforcement discretion for the use of a qualified health claim.
- The FDA does not “approve” qualified health claim petitions.

## Qualified Health Claims





# Qualified Health Claims

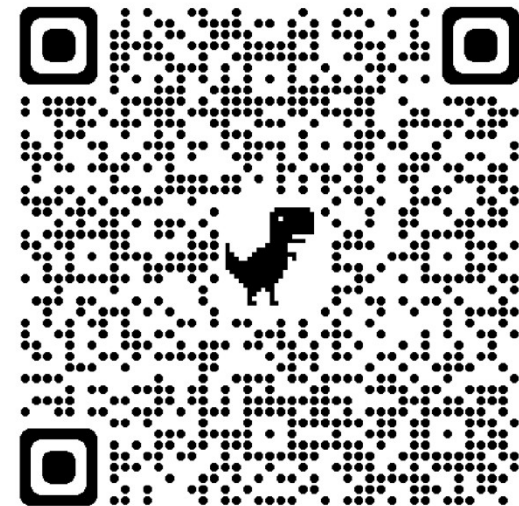
For a QHC petition with credible scientific evidence, the FDA issues a Letter of Enforcement Discretion including specific claim.

## For example:

**“Psyllium husk may reduce the risk of type 2 diabetes, although the FDA has concluded that there is very little scientific evidence for this claim”**

**“Inconsistent and inconclusive scientific evidence suggests that diets with adequate magnesium may reduce the risk of high blood pressure (hypertension), a condition associated with many factors.”**

## Qualified Health Claims: Letters of Enforcement Discretion

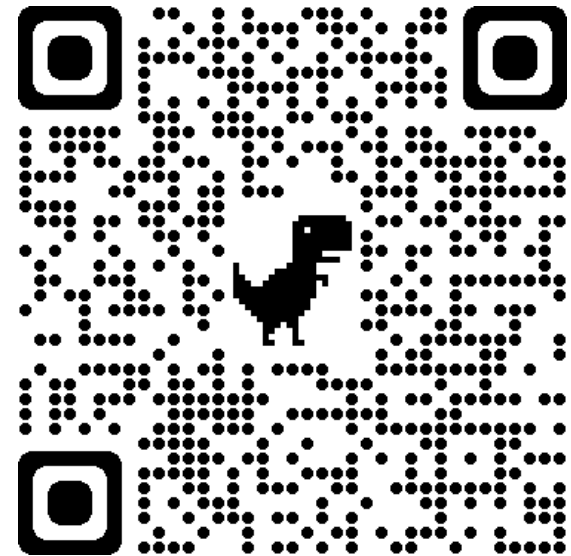


# Detecting Drug/Disease Claim Labeling

# Defining “Disease Claims”

- 21 CFR 101.93(g)(1):
  - A “disease” is damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease) OR
  - A state of health leading to such dysfunctioning (e.g., hypertension)

TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER B - FOOD FOR HUMAN CONSUMPTION  
PART 101 [FOOD LABELING](#)



# Defining “Disease Claims”

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- 21 CFR 101.93(g)(2)(i-x):

What are the criteria for determining if a statement is a disease claim?

- (i) Has an effect on a specific disease or class of diseases
  - This included IMPLICIT and EXPLICIT claims

Explicit

AIDS

Cancer

Implicit

Prevent wasting in people with  
weakened immune system

Prevent spread of neoplastic cells

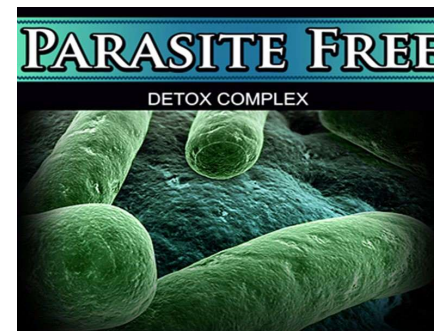
- (ii) Has an effect on a characteristic sign or symptom of a disease
  - *“Lowers your sugar balance to promote a more enjoyable lifestyle”*

## Defining “Disease Claims”

- 21 CFR 101.93(g)(2)(i-x):

What are the criteria for determining if a statement is a disease claim?

- (iii) Has an effect on an abnormal state associated with a natural state or process
  - *“Helps relieve minor chest pains” - “For cold and flu symptom relief”*
- (iv) Has an effect on a disease by:
  - name of product
  - formulation
  - citation of a publication
  - use of the term “disease”
  - use of pictures, vignettes, etc.



# Defining “Disease Claims”

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- 21 CFR 101.93(g)(2)(i-x):

What are the criteria for determining if a statement is a disease claim?

- (v) Belongs to a class of products intended to treat, cure, prevent, mitigate disease
  - Claiming membership in a drug product class:  
*“Antibiotic Aid” – “Worm Be Gone” (Anthelmintic) – “Pain Away” (Analgesic)*
- (vi) Is a substitute for a disease therapy or agent (agent must be for a disease)
  - May include implied claims: “fewer side effects than...”, “safer than...”
  - *“Herbal Viagra” – “Nature’s Aspirin” – “Diabetes Chill-Out”*

# Defining “Disease Claims”

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- 21 CFR 101.93(g)(2)(i-x):

What are the criteria for determining if a statement is a disease claim?

- (vii) Augments a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure, or prevent a disease or class of diseases
  - *“Helps maintain blood sugar when taking insulin”*
  - *“Replaces lost microminerals while on chemotherapy”*
- (viii) Has a role in the body’s response to a disease or disease vector
  - *“Controls the body’s antiviral response”*
  - *“Increases your immune system response during allergy season”*

# Defining “Disease Claims”

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- 21 CFR 101.93(g)(2)(i-x):

What are the criteria for determining if a statement is a disease claim?

- (ix) Treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse events constitute diseases
  - *“Helps people taking antibiotics maintain normal intestinal flora”*
- (x) Otherwise suggests an effect on a disease or diseases
  - Allows for implied disease claims that do not fit in the other nine criteria
  - The nine criteria are not an exhaustive list of all claims believed to be disease claims





# QUESTIONS?

**Siobhan Gallagher Taylor**

Dietary Supplement National Expert

[Siobhan.Taylor@fda.hhs.gov](mailto:Siobhan.Taylor@fda.hhs.gov)

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