5 **Required** Statements

2 **Label** Panels

15 **Mandatory** Nutrients

3 **Claim** Types

12 **Pre-Print** Checks

Get the label right before it prints:

the FDA Dietary Supplement Labeling Guide.

Every bottle **North West PharmaNaturals (NWPN)** fills carries a brand's label, and under FDA rules that label is the brand's responsibility. **FDA does not review or approve supplement labels before they reach the market.** Mistakes surface after launch, when they cost the most to fix.

This guide condenses FDA's **Dietary Supplement Labeling Guide** and **21 CFR Part 101** into a working reference: the five required statements, where each one goes, how to build a Supplement Facts panel, what you can claim, and the other checks to clear before you approve a proof.



5 STATEMENTS
What every label must say, and the regulation behind each.

2 PANELS
What goes on the front, what goes beside it, and what can't sit between.

15 NUTRIENTS
The current mandatory list, including what changed in 2016.

3 CLAIM TYPES
Nutrient content, health and structure/function, and the rules for each.

12 CHECKS
Run through these before you sign off on a label proof.

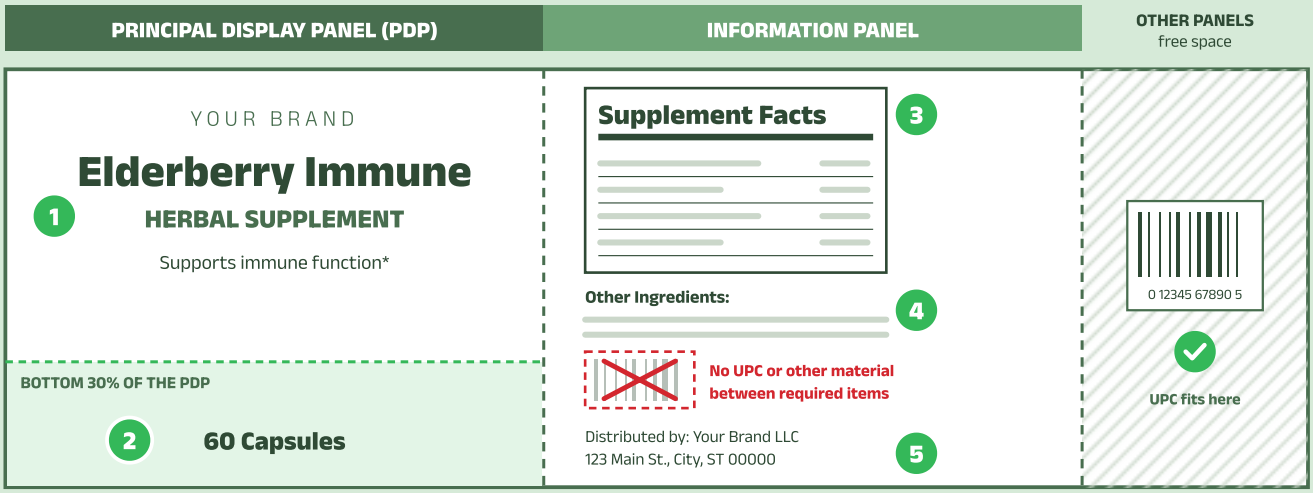
North West PharmaNaturals

5 Required Statements

SECTION 1

FIVE STATEMENTS, TWO PANELS, NO EXCEPTIONS

Every dietary supplement label must carry these five elements, on the Principal Display Panel (the front) or the Information Panel (usually the panel immediately to its right).



A wrap label laid flat. Turn the bottle to the right from the front and the Information Panel is the next thing you see.

STATEMENT OF IDENTITY 1

The product name, including "dietary supplement" or an allowed variation.

PDP ·21 CFR 101.3(a)

NET QUANTITY OF CONTENTS 2

The amount in the package, by count, weight or measure.

PDP ·21 CFR 101.105(a)

NUTRITION LABELING 3

The "Supplement Facts" panel.

Info Panel or PDP ·21 CFR 101.36

INGREDIENT LIST 4

The full ingredient declaration.

Info Panel or PDP ·21 CFR 101.4(a)(1)

NAME AND PLACE OF BUSINESS 5

Of the manufacturer, packer or distributor.

Info Panel or PDP ·21 CFR 101.5

PLACEMENT RULES

- **Front panel:** the statement of identity and net quantity must go on the PDP, the panel most likely seen at retail.
- **Information Panel:** the Supplement Facts panel, ingredient list and name/address go here if they aren't on the PDP.
- **Nothing in between:** no "intervening material" (a UPC barcode, for example) may sit between required items on the Information Panel.
- **Address:** city, state and ZIP are always required. A street address is required only if the business isn't listed in a current phone or city directory.

LEGIBILITY RULES FOR ALL REQUIRED TEXT



1/16 in.
Minimum letter height. The bar is printed at actual size.

3× rule
Letters no more than 3 times as high as they are wide.

Contrast
Sufficient contrast against the background.

All required text must be prominent, conspicuous and easy to read.

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Aa

Identity
& Quantity
SECTIONS 2 & 3

SAY WHAT IT IS AND HOW MUCH IS INSIDE

The two statements that must appear on the front panel, and the type size each one needs.

2 STATEMENT OF IDENTITY

21 U.S.C. 321(ff)(2)(C), 343(s)(2)(B); 21 CFR 101.3

ACCEPTABLE STATEMENTS OF IDENTITY

Dietary Supplement	Acceptable on its own
Herbal Supplement	"Dietary" replaced by the ingredient type
Calcium Supplement	"Dietary" replaced by the ingredient name
Bee Pollen Supplement	"Dietary" replaced by the ingredient name

- **Must include the term "dietary supplement,"** or replace "dietary" with the type of ingredient or the ingredient name.
- **On the PDP** (and any alternate PDP), **in bold type**, in a size reasonably related to the most prominent text on the panel.
- **On lines generally parallel** to the base of the package.
- **Brand names are not a substitute** for the statement of identity, and should not be more prominent than it.

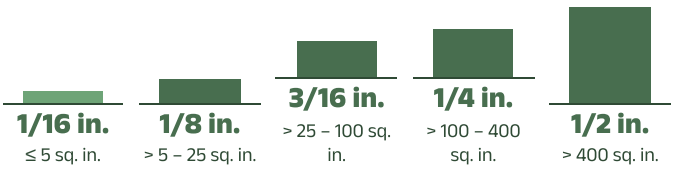
3 NET QUANTITY OF CONTENTS

21 CFR 101.105

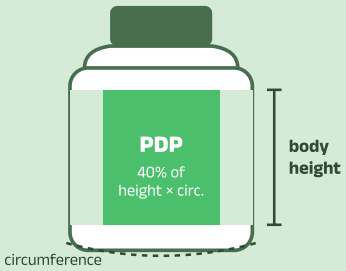
- **States the amount** by weight, measure or numerical count (e.g., "100 tablets").
- **Weight or measure needs both** metric (g, kg, mL, L) and U.S. customary units (oz, lb, fl oz).
- **Bottom 30% of the PDP,** as a distinct item, in lines parallel to the base. Exception: a PDP of 5 sq. in. or less.
- **No exaggerating qualifiers** such as "jumbo" or "full gallon."

✓ **100 Tablets** ✓ **Net Wt. 8 oz (227 g)** ✗ ~~**Net Wt. 227 g**~~ ✗ ~~**Jumbo 100 Tablets**~~

MINIMUM TYPE SIZE SCALES WITH PDP AREA



Bars show minimum type height at actual size when printed at 100%.



HOW TO MEASURE YOUR PDP AREA 21 CFR 101.1

RECTANGULAR PACKAGE	**BOTTLE OR JAR**
height × width of the front panel	40% of (body height × circumference), leaving out the shoulder and neck

Worked example: a bottle 2.5 in. across (about 7.85 in. around) with a 3 in. body: 0.4 × 3 × 7.85 ≈ **9.4 sq. in.**, so the net quantity needs type at least **1/8 in.** tall.

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15

Mandatory Nutrients

SECTION 4 · SUPPLEMENT FACTS

ANATOMY OF A SUPPLEMENT FACTS PANEL

The core content every panel needs, pinned to an illustrative example.

21 CFR 101.36; 101.9

Supplement Facts

Serving Size 2 Capsules

Servings Per Container 30

	Amount Per Serving	% Daily Value
Vitamin C (as ascorbic acid)	500 mg	556%
Vitamin D (as cholecalciferol)	25 mcg	125%
Zinc (as zinc citrate)	15 mg	136%
Quercetin	100 mg	†
Immune Blend	300 mg	†
Elderberry (Sambucus nigra) fruit extract, Echinacea (Echinacea purpurea) root, Ginger (Zingiber officinale) root		

† Daily Value not established.

Other Ingredients: Hypromellose (capsule), rice concentrate.

Illustrative example only, not a real product. Amounts and %DVs are calculated against current Daily Values.

1 TITLE
"Supplement Facts," bold, in larger type than everything else in the panel, enclosed in a box with hairline rules.

2 SERVING INFORMATION
"Serving Size" (exact wording required) and "Servings Per Container." Servings may be omitted if identical to the net quantity statement.

3 DV NUTRIENTS, IN FIXED ORDER
Vitamin A, C, D, E, K, thiamin, riboflavin, niacin, B6, folate, B12, biotin, pantothenic acid, then calcium, iron, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, sodium, potassium.

4 OTHER DIETARY INGREDIENTS
Ingredients without an established DV (e.g., phosphatidylserine) go below the DV nutrients, by common name and weight.

5 PROPRIETARY BLENDS
Labeled "Proprietary Blend" or a fanciful name, with total blend weight, then each ingredient indented in descending order of predominance by weight.

6 FOOTNOTE SYMBOL
Ingredients without a DV are flagged with a symbol that reads "Daily Value Not Established."

7 OTHER INGREDIENTS
Placed immediately below the panel. See Section 5.

MANDATORY WHEN PRESENT IN MORE THAN INSIGNIFICANT AMOUNTS current rules, per FDA's 2016 label-revision final rule

Total calories · Total fat · Saturated fat · Trans fat · Cholesterol · Sodium · Total carbohydrate · Dietary fiber · Total sugars · **Added sugars** · Protein · **Vitamin D** · Calcium · Iron · **Potassium**

REMOVED IN 2016
~~Calories from fat~~

BECAME MANDATORY
Added sugars · **Vitamin D** · **Potassium**

BECAME VOLUNTARY
Vitamin A · Vitamin C

The original 2005 Guide still shows the older list. Other vitamins and minerals from the standard list, including vitamins A and C, are declared only if added for supplementation purposes or if a claim is made about them.

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%DV

Panel Rules

SECTION 4 CONTINUED

%

NUMBERS, FORMAT AND WHO CAN SKIP THE PANEL

How to state %DV, how the panel must look at each package size, how much must actually be in the product, and who is exempt.

PERCENT DAILY VALUE (%DV)

- **Required for every dietary ingredient with an established DV.** Protein's %DV may be omitted.
- **Omit several specific %DVs** on labels for infants, children under 4, and pregnant or lactating women (see Guide Chapter IV, Q23).
- **Round to the nearest whole percent.** Use "Less than 1%," not "0%," when a declared amount rounds to zero.

✓ Less than 1% ✕ ~~0%~~

- **"Percent Daily Values are based on a 2,000 calorie diet"** is required only if fat, saturated fat, carbohydrate, fiber or protein is declared. The 2,000/2,500-calorie comparison chart used on food labels is **not** required.

FORMAT

ONE TYPEFACE
A single, easy-to-read typeface.

ONE COLOR
Black (or one color) type on a white or neutral background, where practical.

UPPER & LOWERCASE
All caps allowed only on packages under 12 sq. in.

≥1 PT LEADING
With hairlines between ingredient rows.

Aa **8 pt** standard minimum body text

Aa **6 pt** column headings and footnotes

Aa **4.5 pt** floor for small packages

PACKAGE SIZE	MIN. TYPE	NOTES
SMALL under 12 sq. in.	**4.5 pt**	May substitute a phone number or address for the panel if the label bears no claims.
INTERMEDIATE 12–40 sq. in.	**6 pt** 4.5 pt if listing many ingredients	Tabular or linear format allowed; approved abbreviations permitted.

COMPLIANCE TOLERANCES



≥100% of the labeled amount for **added** dietary ingredients (allowing for analytical variance).



≥80% of the labeled amount for **naturally occurring** dietary ingredients.

Shelf life matters here: the amount must still meet the label after storage, not only at release.

EXEMPTIONS FROM THE PANEL 21 CFR 101.36(h)

The label must bear no claims or nutrition information.

- **Small businesses:** $50,000 or less per year in food sales to consumers, or $500,000 or less in total sales.
- **Low-volume products:** fewer than 100,000 units per year, a firm with fewer than 100 full-time-equivalent employees, and an annual notice filed with FDA.
- **Bulk product** shipped for use in manufacturing other supplements, not sold directly to consumers in that form.

Ingredient List

SECTION 5 ·21 CFR 101.4

EVERYTHING ELSE IN THE CAPSULE, IN THE RIGHT ORDER

The ingredient list covers what the Supplement Facts panel doesn't: capsule shells, flow agents, fillers, flavors and colors.

Is every ingredient already named as a **source** in the Supplement Facts panel, e.g., "Calcium (as calcium carbonate)", with no other additives?

YES

No ingredient list required.
The panel already discloses everything.

NO

Ingredient list required.
Header "Other Ingredients" if some ingredients are named in the panel as sources; otherwise "Ingredients."

HOW TO SET THE LIST

- **Strict descending order of predominance by weight,** including added water.
- **Immediately below the Supplement Facts panel,** or immediately to its right if there's no room below.
- **Minimum 1/16-inch type.**

Microcrystalline cellulose — 1st ·most by weight

Hypromellose (capsule)

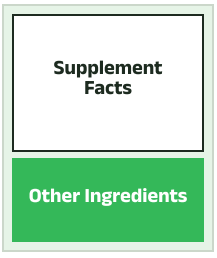
Rice concentrate

Silicon dioxide — last ·least

NAMING FLAVORS, COLORS AND PRESERVATIVES

FLAVORS & SPICES	Common names, or generic terms: "natural flavor," "artificial flavor," "spice."
CERTIFIED COLORS	Specific or abbreviated names. **e.g., "FD&C Red No. 40"**
NON-CERTIFIED COLORS	"Artificial Color," or the common name.
CHEMICAL PRESERVATIVES	The name plus its function. **e.g., "... to retard spoilage"**

WHERE THE LIST GOES



BELOW THE PANEL
The default.



TO ITS RIGHT
Only if there's no room below.

PUTTING IT TOGETHER

Other Ingredients: Microcrystalline cellulose, hypromellose (capsule), rice concentrate, natural flavor, FD&C Red No. 40, ascorbic acid (to retard spoilage), silicon dioxide.

Illustrative only. "Other Ingredients" because the dietary ingredients are already named in the panel; listed by weight, color by its certified name, preservative with its function.

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3

Claim Types

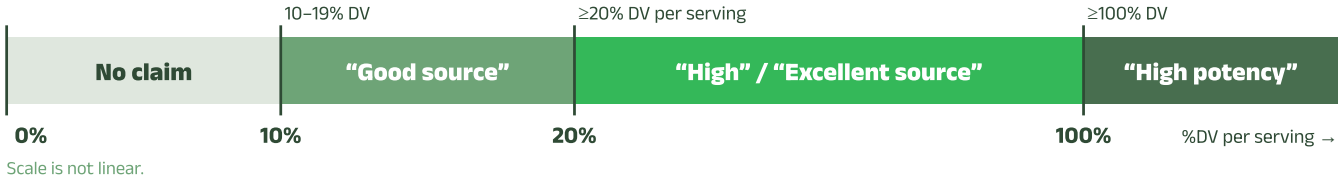
SECTION 6 ·CLAIMS

KNOW WHICH CLAIM YOU'RE MAKING BEFORE YOU PRINT IT

Each claim type has its own gate. The words on the label decide which rules apply.

	NUTRIENT CONTENT	HEALTH	STRUCTURE/FUNCTION
WHAT IT SAYS	The level of a nutrient "high," "good source," "free," "high potency"	A link between a substance and disease risk reduction	A nutrient's role in maintaining body structure or function "supports bone health"
FDA PRE-APPROVAL	**DEFINED TERMS ONLY** 21 CFR 101, Subpart D	**REQUIRED** Authorized, or FDA "qualified" status	**NOT NEEDED** but three conditions apply
NOTIFY FDA IN 30 DAYS	No	No	**Yes**
FDA DISCLAIMER	No	Qualified claims carry an agency-approved disclaimer	**Yes, exact wording**
RULE	21 CFR 101.13, 101.54	21 CFR 101.14	21 CFR 101.93

A NUTRIENT CONTENT CLAIMS



Scale is not linear.

- **Only claims and synonyms already defined** in 21 CFR 101, Subpart D may be used. A Supplement Facts panel is mandatory whenever a nutrient content claim is made.
- **"High potency" on multi-nutrient products:** ≥100% DV for at least two-thirds of the vitamins and minerals present at ≥2% DV.
- **Claim type size** may be no larger than 2× the statement-of-identity type size.

DISCLOSURE STATEMENT
required when a nutrient content claim is made and the product exceeds, per serving:

13 g	4 g	60 mg	480 mg
fat	saturated fat	cholesterol	sodium

Boldface, immediately adjacent to the claim, no smaller than the net-quantity type-size rules (min. 1/16 in., or 1/32 in. for very small restaurant-serving packages).

B HEALTH CLAIMS

21 CFR 101.14

AUTHORIZED
Requires significant scientific agreement and prior FDA authorization (see Guide Appendix E).

QUALIFIED
FDA-issued "qualified health claim" status, with an agency-approved disclaimer (Appendix F).

NEW CLAIM
Requires a petition under 21 CFR 101.70.

30

Days to Notify

SECTION 6 · STRUCTURE/FUNCTION

NO PRE-APPROVAL, BUT THREE CONDITIONS

"Supports bone health" needs no FDA sign-off. It does need evidence, a disclaimer and a notification.

1 SUBSTANTIATION	2 MANDATORY DISCLAIMER	3 FDA NOTIFICATION
You must hold evidence that the statement is truthful and not misleading.	Exact required wording, with no modifications. Placement and type rules below.	Due no later than 30 days after you first market the product with the claim.

Supports bone health*

***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.**

THE DISCLAIMER

- Use **"These statements"** if the label carries more than one claim.
- **Placement:** immediately adjacent to the claim, or elsewhere on the same panel, linked by a matching symbol (e.g., an asterisk) and set inside a box.
- **Minimum 1/16-inch bold type.**

FILING THE NOTIFICATION



- **Electronic (encouraged):** FDA's Centralized Online Submission Module (COSM) ePortal, which provides confirmation of receipt and status updates.
- **By mail (still accepted):** Food and Drug Administration (HFS-810), Office of Dietary Supplement Programs, 5001 Campus Drive, College Park, MD 20740-3835.

THE NOTIFICATION MUST INCLUDE

1. Name and address of the manufacturer, packer or distributor.
2. The exact text of the claim.
3. The name of the dietary ingredient or supplement that is the subject of the claim.
4. The name of each product bearing the claim, including brand name. Generic phrases like "other brands" are not allowed.
5. The signature of a responsible individual certifying accuracy, and that substantiation exists.

SAME RULE, TWO MORE CLAIM TYPES

General well-being claims and classical nutrient deficiency disease claims also need notification. Together with structure/function claims they're called **"403(r)(6) claims."**

NO NOTIFICATION NEEDED FOR

Authorized health claims, qualified health claims or nutrient content claims.

21 CFR 101.93; 21 U.S.C. 343(r)(6); FDA, Notifications for Structure/Function and Related Claims in Dietary Supplement Labeling.

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7

Other Checks

SECTION 7

OTHER REQUIREMENTS TO CHECK, AND WHO ENFORCES THEM

Not every rule on a supplement label comes from FDA. Know which agency you'd answer to.

FDA

IRON WARNING

Solid-dose products containing iron must bear this verbatim, in a hairline box on the Information Panel (and the outer package, if any).

> **WARNING:** Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

FDA

NEW DIETARY INGREDIENTS (NDIs)

An ingredient not marketed in the U.S. before **Oct. 15, 1994** generally requires a premarket safety notification to FDA at least **75 days** before marketing (see Guide Chapter VII).

FDA

EXPIRATION DATING

Not required, but permitted if supported by data showing it is not false or misleading.

U.S. CUSTOMS

COUNTRY OF ORIGIN

Imported products must conspicuously show the English name of the country of origin (Tariff Act of 1930). Enforced by U.S. Customs, not FDA.

CUSTOMS / FTC

"MADE IN USA"

Regulated by U.S. Customs and the FTC, not FDA.

USDA

ORGANIC CLAIMS

Regulated by USDA's National Organic Program, not FDA.

FDA

NO FDA LABEL PRE-APPROVAL

FDA does not review or approve dietary supplement labels before marketing. The firm is responsible for compliance, and FDA enforces after the product is on the market.

WHO CHECKS YOUR LABEL BEFORE IT SHIPS?

Not FDA. Three checks stand between your proof and a costly reprint: a careful in-house review, a manufacturer that reads every label it fills, and regulatory counsel for anything novel.

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Pre-Print Checklist

BEFORE YOU APPROVE A PROOF

TWELVE CHECKS, ONE COMPLIANT LABEL

Run every proof through this list. Each line points back to a section of this guide.

THE PRE-PRINT CHECKLIST

- [ ] **Statement of identity** on the PDP, bold, with "dietary supplement" or an allowed variation. §2
- [ ] **Net quantity** in the bottom 30% of the PDP, at the right type size; metric + U.S. units for weight or measure. §3
- [ ] **Panel, ingredients and name/address** on the Info Panel or PDP, with nothing in between. §1
- [ ] **All required text** at least 1/16 in., clear and high contrast. §1
- [ ] **Current nutrient list:** added sugars, vitamin D, potassium; no "calories from fat." §4
- [ ] **DV nutrients in the fixed order,** %DV rounded, "Less than 1%" where needed. §4
- [ ] **No-DV ingredients flagged** †; blends show total weight and descending order. §4
- [ ] **Ingredient list** directly below the panel, by weight, colors and preservatives named correctly. §5
- [ ] **Nutrient content claims** use defined terms, meet thresholds, and carry any required disclosure. §6
- [ ] **Structure/function claims** substantiated, with the exact disclaimer in bold. §6
- [ ] **FDA notified** within 30 days of first marketing each claim. §6
- [ ] **Iron warning, country of origin and NDI status** checked; testing supports the label amounts. §4, §7

KNOW WHERE THIS GUIDE STOPS

WHAT IT COVERS

The core requirements of FDA's Guide (Chapters I–VI and VIII), which address roughly 80–90% of label-compliance questions for a typical finished product.

WHAT IT LEAVES OUT

The full NDI notification procedure (Chapter VII) and the Daily Value and claim tables (Appendices B–F).

WHEN TO GO FURTHER

For products with claims, children- or pregnancy-specific labeling, or new ingredients, consult the full guide, 21 CFR Part 101, or regulatory counsel.

FROM FORMULA TO FINISHED LABEL.

Talk to NWPN about your next product:
info@northwestpn.com · **northwestpn.com**

- ✓ Label review on every order
- ✓ CCOF certified organic manufacturer
- ✓ A COA with every lot
- ✓ A dedicated project contact
- ✓ NSF cGMP certified (NSF/ANSI 455-2)
- ✓ FDA-registered facility
- ✓ We source organic pullulan capsules
- ✓ Family-owned, 40+ years

BONUS · PAIR THIS WITH OUR LABEL SELF-AUDIT

This guide explains the rules. Our free **10-minute Label Self-Audit** walks your actual label through them, line by line.

This guide is condensed from FDA's Dietary Supplement Labeling Guide (April 2005; Chapter II updated January 2016), with Supplement Facts nutrient requirements and structure/function notification procedures updated to current FDA rules as of October 2026. FDA's guide is nonbinding guidance and covers 21 CFR Part 101. Source: fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/dietary-supplement-labeling-guide. This summary is for educational purposes and is not legal or regulatory advice.

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