5 **Must**-Haves

6 **Forbidden** Words

1 **Disclaimer** Rule

7 **Blind** Spots

A 10-minute label self-audit for dietary supplement brand owners.

At **North West PharmaNaturals (NWPN)**, our compliance and quality teams see a lot of labels, and we'd like to share a self-audit framework built around **Current Good Manufacturing Practices (cGMP)** and **FDA labeling regulations**, so you can catch the common misses before they cause problems.

Pull up your current label or newest proof and work through the four sections in order. A checklist on the last page lets you mark off each item as you go.



5 MUST-HAVES
The statements every label is legally required to carry, and the panel each one lives on.

6 FORBIDDEN WORDS
The disease-claim words that turn a supplement into an unapproved drug.

1 DISCLAIMER RULE
The exact DSHEA wording, where it goes, and how big it has to be.

7 BLIND SPOTS
The technical misses our compliance team catches most often, with the fix for each.

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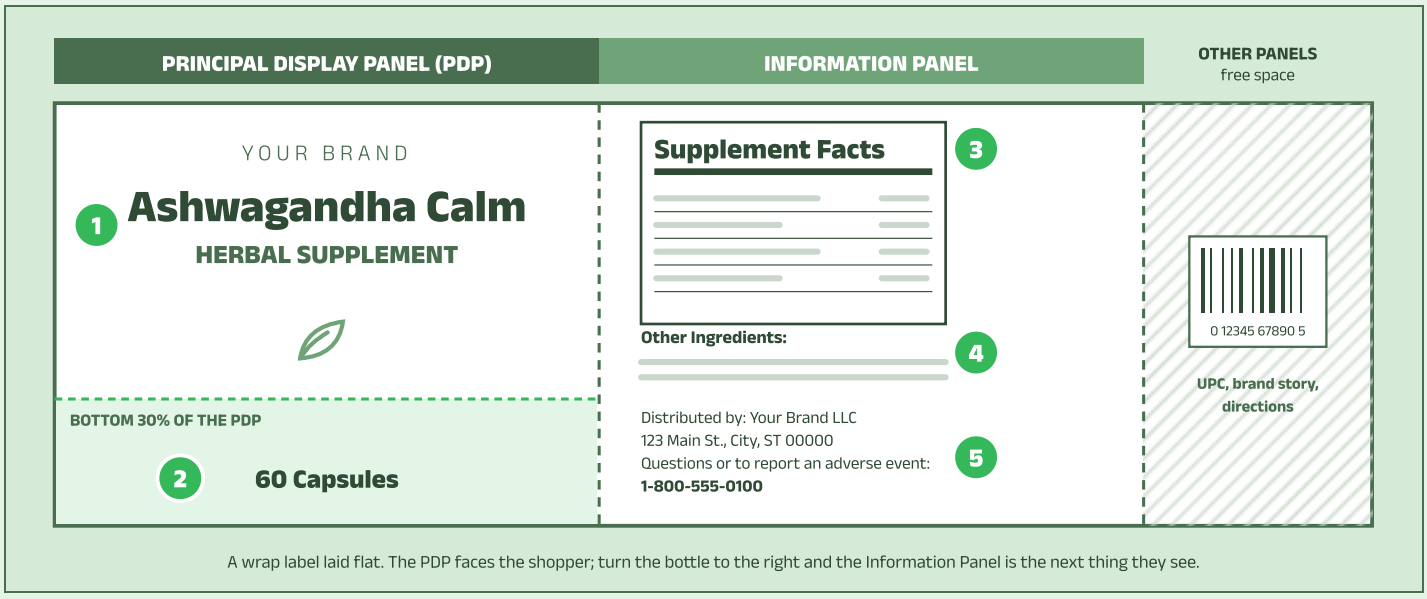
5

Must-Haves

PER 21 CFR 101

TWO ZONES, FIVE MUST-HAVES

A dietary supplement label is split into two distinct visual zones: **the Principal Display Panel (PDP)**, the front of the package, and **the Information Panel (IP)**, usually directly to the right of the PDP.



A wrap label laid flat. The PDP faces the shopper; turn the bottle to the right and the Information Panel is the next thing they see.

HERE'S WHAT EACH ONE IS **LEGALLY REQUIRED** TO CARRY.

1	**STATEMENT OF IDENTITY** **PRODUCT NAME + THE WORDS "DIETARY SUPPLEMENT"** Must be clearly identified using the term "Dietary Supplement," or a descriptive term substituting the ingredient name (e.g., "Vitamin C Supplement"). Bold font, reasonably sized, parallel to the base of the package.	PDP
2	**NET QUANTITY OF CONTENTS** **FRONT PANEL, IN THE BOTTOM 30%, PARALLEL TO THE BASE** Must include both metric and U.S. customary units for weight or measure, e.g., **Net Wt. 60 g (2.1 oz)** for powders, or **60 Capsules** for solid oral dosage forms.	PDP
3	**SUPPLEMENT FACTS PANEL (SFP)** **ALL REQUIRED NUTRIENTS + FORMATTING PER 21 CFR 101.36** A strictly formatted box detailing serving size, servings per container, and dietary ingredients. All body text must be a uniform size no smaller than **8 pt**, column headings and footnotes may run as small as **6 pt**, and small packages may use a minimum of **4.5 pt**.	IP
4	**INGREDIENT STATEMENT "OTHER INGREDIENTS"** **ANYTHING NOT ALREADY LISTED IN THE SF PANEL** Must live immediately below or adjacent to the SFP. Lists excipients, binders, fillers, capsule shell components, or flavors in descending order of predominance by weight.	IP
5	**NAME, PLACE OF BUSINESS & AER CONTACT** **MANUFACTURER/DISTRIBUTOR ADDRESS, PLUS A WAY TO REPORT ADVERSE EVENTS** Must list the name and place of business of the manufacturer, packer, or distributor (city, state, ZIP), qualified with "Distributed by" or "Manufactured for" if a distributor's name is used. That same domestic address or phone number also satisfies the federal adverse-event-reporting requirement.	IP

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6 Forbidden Words

WORD HEATMAP

DISEASE VS. STRUCTURE/FUNCTION

Six words turn a supplement into an unapproved drug the moment they land on your label. Here's how to read the risk, word by word.

RED · DISEASE CLAIMS

WARNING-LETTER TERRITORY.

CURES **TREATS** **HEALS** **PREVENTS** **DIAGNOSES** **MITIGATES**

These turn a supplement into an unapproved drug.

YELLOW · DEPENDS ON CONTEXT

SAFER TO SWAP FOR "SUPPORTS" OR "HELPS MAINTAIN."

IMPROVES **BOOSTS** **INCREASES** **REDUCES**

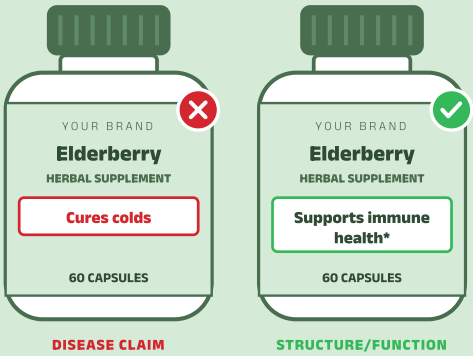
Fine with "energy" or "focus." Not fine with "blood pressure" or "blood sugar." **"Reduces" is the riskiest word here: it almost always pairs with a symptom.**

GREEN · STRUCTURE/FUNCTION

SELLS WITHOUT BREAKING THE LAW.

SUPPORTS **PROMOTES** **MAINTAINS** **HELPS MAINTAIN** **ENHANCES** **AIDS**

Legal, DSHEA-compliant language.



SAME BENEFIT, SAFER WORDS

~~Cures colds~~	→ **Supports immune health***
~~Treats insomnia~~	→ **Promotes restful sleep***
~~Reduces anxiety~~	→ **Supports a healthy stress response***
~~Lowers cholesterol~~	→ **Helps maintain cholesterol levels already within the normal range***

A swap fixes the word, not the meaning. If images, testimonials or the product name still point to a disease, it is still a disease claim. Every green-tier claim also needs the disclaimer on the next page.

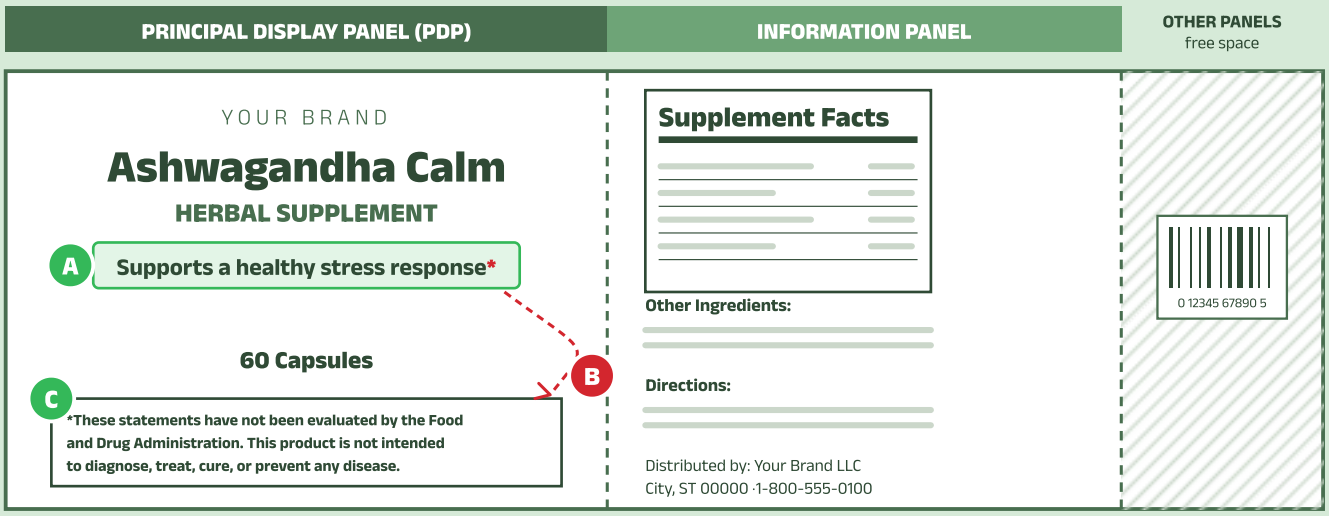
1

Disclaimer Rule

DSHEA · 21 CFR 101.93

THE DISCLAIMER RULE

If your label contains any structure/function claims, it must display the standard statutory DSHEA disclaimer, and it has to follow exact rules for wording, placement, and type size.



The claim sits on the front, so the disclaimer does too. If the same claim also appears on the side panel, that panel needs its own.

THE REQUIRED TEXT — A

The exact statutory DSHEA disclaimer wording

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

Use "This statement has" when the label carries only one claim. No other edits to the wording.

LOCATION — B

Same panel as the claim, linked by symbol, boxed

Must appear on every panel that carries the structure/function claim, linked directly to the claim via a symbol (like an asterisk *), and enclosed within a text box when it isn't placed right beside the claim.

Common miss: the claim is on the front, but the disclaimer only appears on the back.

TYPE REQUIREMENTS — C

Boldface type, at least 1/16 inch, based on the lowercase letter "o"

Must appear in boldface type, at least 1/16 of an inch (approx. 4.5 pt) based on the lower-case letter "o," or the same size as the "Other Ingredients" statement, whichever is larger.

o

1/16 in. Printed at actual size. Measure the "o" on your proof against it.

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7

Blind Spots

FREQUENT FINDINGS

7 COMMON LABELING BLIND SPOTS

These are the technical infractions our compliance team catches most frequently.

	ERROR	FIX
1	**NET (ACTIVE) WEIGHT VS.** GROSS RAW MATERIAL WEIGHT A raw material's net weight, the actual active compound, isn't always the same as its gross weight, since many raw materials include carriers, solvents, or moisture. **Quercetin dihydrate, for example, is only about 95% active by weight, so 100 mg of the raw material only delivers about 95 mg of active quercetin.**	**Gross raw material weight listed as if it were the active ingredient weight** Confirm whether your spec reflects net (active) or gross (as-supplied) weight, then either declare the true net amount or gross up the raw material input to hit your target. **Use about 105.27 mg of quercetin dihydrate to deliver a true 100 mg active.**
2	**OUTDATED DAILY VALUE (DV) UNITS:** IUS VS. MG/MCG Listing vitamin A, D, and E in International Units (IUs), a format the FDA phased out to eliminate confusion around actual nutrient mass and bioavailability.	**Vitamin A, D, and E listed in International Units (IUs)** Transition to the mandatory modern formats: **vitamin A in mcg RAE, vitamin D in mcg** (IUs can still appear in parentheses), and **vitamin E in mg alpha-tocopherol**.
3	**COLONY COUNTS FOR PROBIOTICS** (CFUS) Listing probiotic quantities exclusively in milligrams (mg), a metric that doesn't prove cell viability or functional potency, since microorganisms vary in weight.	**Probiotic quantities listed only in milligrams** FDA draft guidance recommends declaring the weight in mg and the active live colony count in CFUs. **e.g., Lactobacillus acidophilus... 10 mg (5 Billion CFU).** *Not yet binding, but increasingly expected by retailers and auditors.*
4	**VAGUE "AS" STATEMENTS FOR** INGREDIENT IDENTITY Listing a mineral or compound without disclosing its specific molecular source. **e.g., stating "Zinc... 15 mg" with no source named.**	**Mineral or compound listed without its molecular source** The FDA requires the specific chemical form to verify biological safety and identity. Format it as an "as" statement: **"Zinc (as Zinc Citrate)"**

WHY THESE SLIP THROUGH

Most of these aren't design mistakes. They start in the spec sheet: raw material assays, supplier ingredient names, extract ratios. Have whoever owns the formula sign off on the Supplement Facts panel, not just the designer.

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7 Blind Spots
CONTINUED

"IF A GRAPHIC DESIGNER WROTE YOUR LABEL WITHOUT A REGULATORY PASS, IT PROBABLY HAS AT LEAST ONE VIOLATION HIDING IN PLAIN SIGHT."

	ERROR	FIX
5	**BRAND NAMES VS.** SCIENTIFIC NAMES FOR BOTANICALS Using a trademarked, commercial brand name in the Supplement Facts panel without the underlying plant's regulatory name.	**Brand name used without the plant's regulatory name** A proprietary brand name is fine to include, but it must be paired with the common name or Latin binomial and the plant part used. **e.g., KSM-66® Ashwagandha Extract (Root) (*Withania somnifera*).**
6	**EXTRACT POTENCY** & EQUIVALENTS Listing an extract ratio without stating the raw material equivalent mass or a standardized active marker percentage. **e.g., "Elderberry 10:1 Extract"**	**Extract ratio given with no equivalent or standardization** Best practice, and increasingly expected for substantiation, is to disclose what the ratio represents. **e.g., 100 mg (equivalent to 1,000 mg of whole elderberry fruit), or standardize to an active component.**
7	**ALLERGEN** OMISSIONS Failing to clearly declare major food allergens. **Milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, soybeans, sesame.**	**Major food allergens not clearly declared** Disclose allergens near the ingredient statement, in plain language. **e.g., "Contains: Soy" directly below Other Ingredients.**

BONUS "Made in the USA"

FTC, NOT FDA · KNOW WHEN YOU NEED MORE WORDS

Per the FTC, an unqualified "Made in the USA" claim requires the product be **"all or virtually all"** made and sourced domestically. If any raw materials are foreign, add a qualifier next to the claim disclosing that.

~~**Made in the USA**~~ → **Manufactured in the USA with globally sourced ingredients**

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Audit
Checklist

MARK EACH LINE ON YOUR PROOF

TEN MINUTES, ONE CLEANER LABEL

Print your label at 100%, then work down this list. Anything you can't tick goes back to your designer before the next print run.

THE SELF-AUDIT

5 MUST-HAVES

- [ ] **Statement of identity** on the PDP, bold, with "Dietary Supplement" or the ingredient name.
- [ ] **Net quantity** in the bottom 30% of the PDP; metric + U.S. units for weight.
- [ ] **Supplement Facts** at 8 pt body text (6 pt headings, 4.5 pt small packages).
- [ ] **Other Ingredients** directly below or beside the SFP, by weight.
- [ ] **Name, city, state, ZIP** and an adverse-event phone or address.

6 FORBIDDEN WORDS

- [ ] **No red-tier words**: cures, treats, heals, prevents, diagnoses, mitigates.
- [ ] **Yellow-tier words** never paired with a disease or symptom.

1 DISCLAIMER RULE

- [ ] **Exact DSHEA wording,** bold, at least 1/16 in., on every panel with a claim.

7 BLIND SPOTS

- [ ] **Net active weights,** modern DV units, and CFUs for probiotics.
- [ ] **"As" statements,** botanical names + plant part, and extract equivalents.
- [ ] **Allergens declared;** "Made in the USA" qualified if needed.

HOW TO RUN IT

1. **USE THE REAL PROOF.**
   Audit the file going to print, at 100% scale, not the mockup or a screenshot.
2. **READ EVERY PANEL.**
   Claims hide on side panels, neck bands and inserts. Each one needs its own disclaimer.
3. **CHECK AGAINST THE SPEC.**
   Compare label amounts to your formula and raw material COAs, not to last year's label.
4. **GET A SECOND SET OF EYES.**
   A regulatory pass before every reprint costs far less than a relabel.

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 FDA LABELING GUIDE

This audit catches the common misses. Our free **FDA Dietary Supplement Labeling Guide** explains every rule behind them, with a 12-point pre-print checklist.

This self-audit is based on FDA's Dietary Supplement Labeling Guide, 21 CFR Part 101 (including 101.36 and 101.93), and the FTC's Made in USA Labeling Rule, as of October 2026. It covers the most common findings, not every requirement. KSM-66® is a trademark of its owner and is shown only as a labeling example. This summary is for educational purposes and is not legal or regulatory advice.

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