



Supplement Advisory Group



APEX[®]
COMPLIANCE

“Gut Health” to Litigation: Marketing Microbiome Supplements Without Stepping Over the Line

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Warning Letter Wednesday Free Resource



Warning Letter Wednesday Posts

A weekly exploration of FDA warning letters and enforcement trends

Search...

Search WLW Posts

August 27, 2025	August 20, 2025	August 13, 2025
 <h3><u>Essential Oil Inhaler Makes Alzheimer's Claims</u></h3>	 <h3><u>"Gum Detoxify" Claims Challenged</u></h3>	 <h3><u>Unallowable Ingredient "Enough" to Trigger Regulatory Action</u></h3>
 Takeaway - Top 10 weirdest and cringiest warning letters	 Takeaway - Qualifying claims makes them easier to substantiate	 Takeaway - Delta-8 is a high-risk ingredient
Top 10 weirdest and cringiest warning letters I've ever seen. FDA issued a warning letter to a company selling an essential oil-looking nasal diffuser for Alzheimer's treatment, dementia, and other...	In an ongoing saga of the dental care and teeth whitening industry, a large company's "gum detoxify" and other claims were challenged by a competitor in this National Advertising Division...	There has been a recent enforcement trend where having an unallowable ingredient in a product can result in a warning letter, even if no disease claims or GMP violations are...

Legal Disclaimer



- This presentation consists of general information. It is intended for general education only.
- Due to the importance of individual facts of every situation, the generalization in this presentation may not necessarily be applicable to all situations. Changes in the law could make parts of this presentation obsolete in the future.
- This information is provided with the understanding that if specific advice is required, the services of a competent attorney should be sought.



What Is A Disease Claim?

- Anything ending in “itis” refers to inflammation-of, such as colitis
- Most things with “anti” in the name, such as anti-inflammatory
- International Classification of Diseases (ICD) code
- The name of any disease or syndrome, such as Crohn's disease or IBS.
- Comparing product to drugs

The Microbiome Marketing Guide: High-Risk vs. Compliant Claims



HIGHER RISK (AVOID)



Disease Treatment vs. Structure Support

Avoid “repair,” “heal,” or “treat”; use “support,” “maintain,” and “healthy function” instead.

Specific Conditions vs. General Wellness

Replace names like IBS, Anxiety, or Infection with digestive comfort, mood, or defenses.

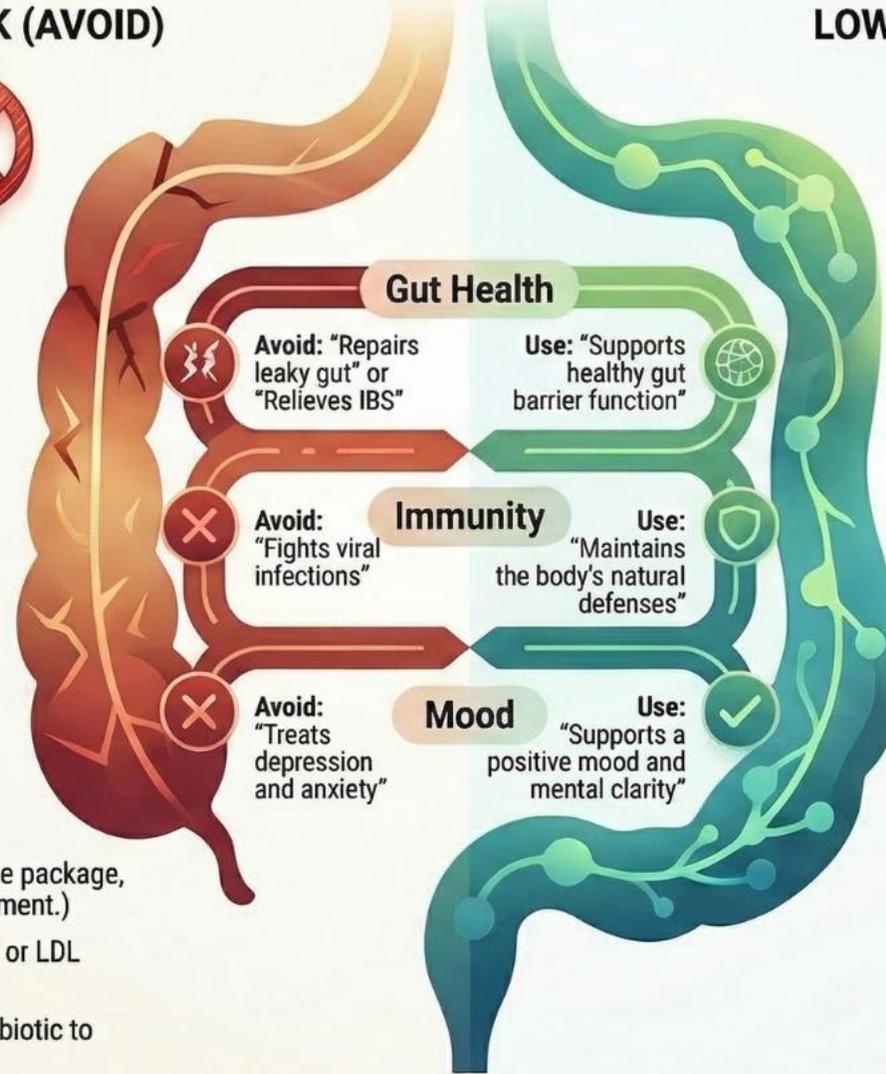
Clinical “Proven” vs. Clinically “Studied”

Use “features a clinically studied strain” rather than claiming a product is “proven” to cure.

Compliance Gut Check

- ⚠️ **Beware the “Net Impression”** (Regulators look at the whole package, including imagery, hashtags, testimonials, and retail placement.)
- ⚠️ **Avoid Biomarker Proxies** (Do not use biomarkers like CRP or LDL cholesterol to imply disease treatment.)
- ⚠️ **No Drug-Adjacent Positioning** (Never suggest using a probiotic to mitigate the side effects of drugs like antibiotics.)

LOWER RISK (USE)



Pro tip: Messaging about “keeping people healthy & within balance” is lower risk than “fixing” issues.

This is why “supporting” language is better than action-oriented words like “promote.”



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Which Product Category



Is This A Dietary Supplement?

- Dietary Ingredients 
- Not represented as a sole item of a meal 
- Not represented as conventional food 
- Intended to be ingested 
- Not subject to drug trials or approvals and no disease claims 



Not a dietary supplement



FDA & Homeopathic Claims

FDA Warning Letter

“WHAT IS IT: Allergy Bee Gone for Kids is a homeopathic remedy that you swab in your nose to fight nasal allergy symptoms, inflammation and to protect your Booger Biome . . . The super honeys in Allergy Bee Gone for Kids are anti-inflammatory, prebiotic, probiotic.”

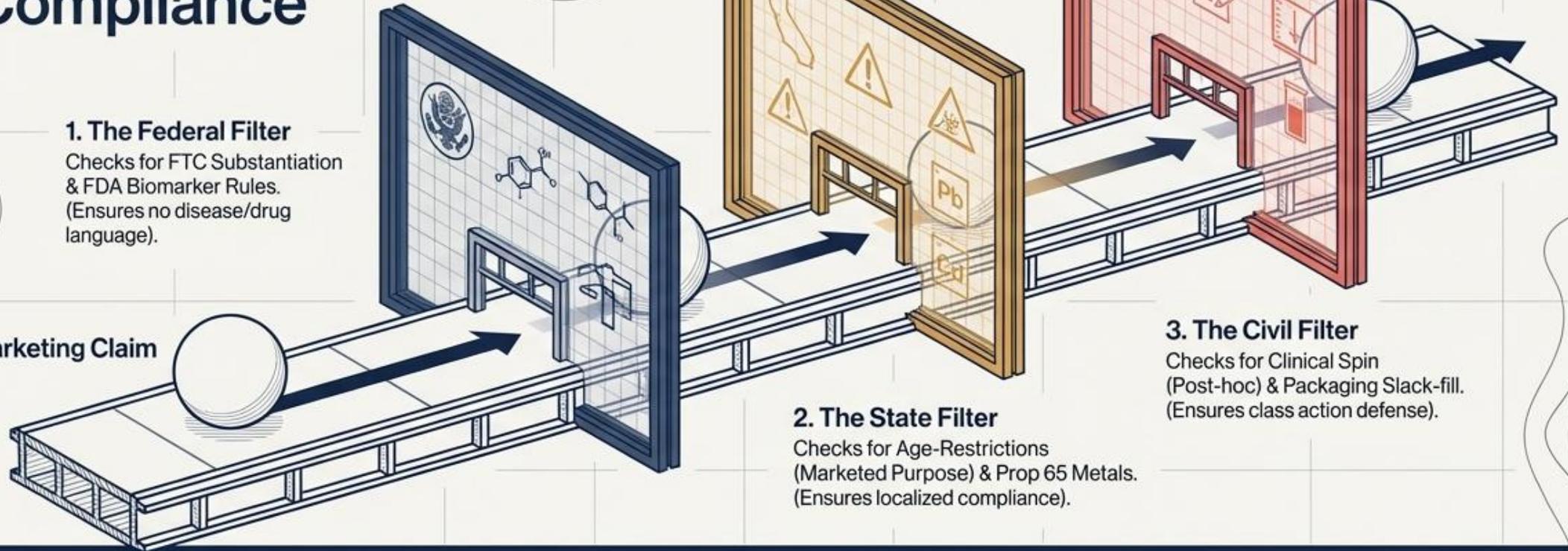


The Gauntlet of Compliance

1. The Federal Filter

Checks for FTC Substantiation & FDA Biomarker Rules. (Ensures no disease/drug language).

Marketing Claim



2. The State Filter

Checks for Age-Restrictions (Marketed Purpose) & Prop 65 Metals. (Ensures localized compliance).

3. The Civil Filter

Checks for Clinical Spin (Post-hoc) & Packaging Slack-fill. (Ensures class action defense).

4. Retailers are the new “regulators” and have their own requirements. Amazon, Whole Foods, etc

State Regulations

The Marketed Purpose Paradox:



Status: Unrestricted Access
Requirement: All Ages



Status: Age-Gated / Behind-the-Counter
Requirement: 18+ ID Required



Pinterest & Website Claims

FDA Warning Letter: Flora Inc

- “Flora’s Travel Care Probiotic is a clinically proven...probiotic that’s been shown to help reduce incidence of traveler’s diarrhea and antibiotic-associated diarrhea while combating pathogenic “bad” bacteria...”



Is “Leaky Gut” a Disease Claim

FDA Warning Letter: Great Lakes Gelatin Company

Under the blog titled "COLLAGEN SUPPLEMENTATION AND GASTROINTESTINAL HEALTH" on your website:

"Many who suffer from leaky gut syndrome use collagen hydrolysate as a supplement to aid in symptom management as well."

Possible Alternatives to “Leaky Gut”

Be truthful and not misleading

- Helps support gut lining integrity
- Gut lining support
- Gut barrier support
- Helps support optimal gut permeability



“Better Than Drugs” Statements = Risky

FDA Warning Letter: JLM Nutritionals, Inc. dba JLM Nutrition—Super Naturals Health

On your blog "Natural IBS Treatment Versus Prescription Treatment For IBS Symptoms" page:

- "On 04/25/16, Jordyn in Los Angeles wrote: . . . I have been suffering for about a year now with IBS-D. . . . I was then diagnosed with IBS-D. I had no idea that IBS could be so debilitating. . . . Luckily I found IBS Formula! I have been off my medications and on this formula for a month. An entire month of no issues, no stomach pains, no missed days of work."

Setting Up Clinical Studies **Correctly**

- Match the claim to the exact strain and dose
- Use pre-specified, clinically meaningful endpoints
- Verify potency through shelf life
- Use caution with disease endpoints

Navigating the Compliance “Red Line” in Microbiome Marketing

Maintaining the “red line” between wellness claims (structure/function) and disease claims (treatment) is crucial to avoid scrutiny from FDA, FTC, and private litigants.

HIGH-RISK “DISEASE” TRIGGERS

The Disease Claim Trap



Terms like “prevent,” “treat,” or “reduce incidence” of infections convert wellness products into unapproved drugs.

Vulnerable Population Escalation



Marketing toward infants/NICU or targeting sepsis/NEC outcomes triggers “biologics-like” enforcement actions.

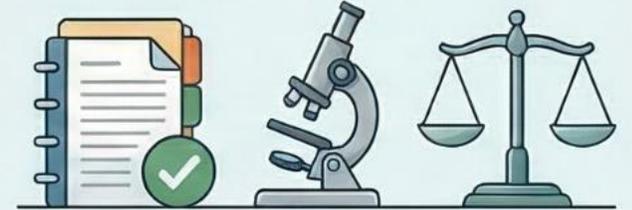


Litigation “Plaintiff Toolkit”

Private lawsuits often target time-bound promises (e.g., “results in hours”) and shelf-life CFU discrepancies.

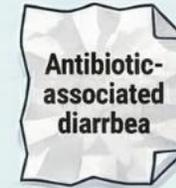
THE COMPLIANCE BLUEPRINT

Substantiation Standards



Brands must match scientific evidence to the “net impression” of the marketing message.

The “Wellness” Rewrite



Replace medical contexts like “antibiotic associated diarrhea” with “supports digestive balance during routine wellness.”

Endorsement Transparency

Influencers must disclose material connections; incentivized sentiment or review suppression triggers FTC risk.



CLAIMS REWRITING GUIDE

HIGH-RISK CLAIM	COMPLIANT REWRITE	RESULT
“Banish bloating in hours”	“Supports digestive comfort; may help with occasional bloating”	
“Rebuild balance lost to antibiotics”	“Supports digestive balance during routine wellness”	
“Clinically Proven” (General)	“Clinically Studied” (Specific to strain and dose)	



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“Clinically Proven + Efficacy Claims : = Lawsuit



“Clinically Proven + Efficacy Claims : = Lawsuit



About this item

- Digestive Enzymes + Probiotics + Prebiotics: Convenient 3-in-1 home or on-the-go gut support solution for relief from occasional bloating, gas, and discomfort from hard to digest foods.
- Lab Proven Multi Enzyme Blend: Shown to digest foods up to 39% more completely and 2 hours faster than your body can on its own. Perfect for gluten exposure or Keto and Paleo diets.
- Clinically Proven DE111 Probiotic: Guaranteed to arrive alive and work within hours in small intestine where 90% of nutrient absorption occurs.
- Botanical Bounty: Turmeric, Ginger, Green Papaya, Inulin, Apple Pectin, Bladderwrack, Fennel, and Wakame all aid gut health and stomach comfort.
- 15 Count Single Empty Tin + 180 Count Tin Replenishment: We suggest taking 1 capsule before each meal or drink to experience digestive delight.

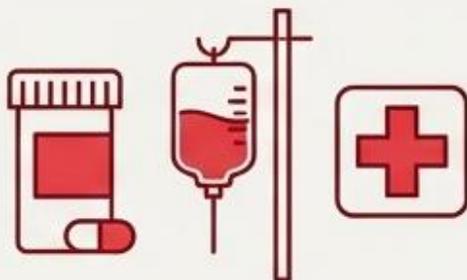
The Net Impression Equation

Compliant Claim

Supports digestive balance during occasional lifestyle or dietary changes



Adjacent Therapy Imagery



Unapproved Drug Claim

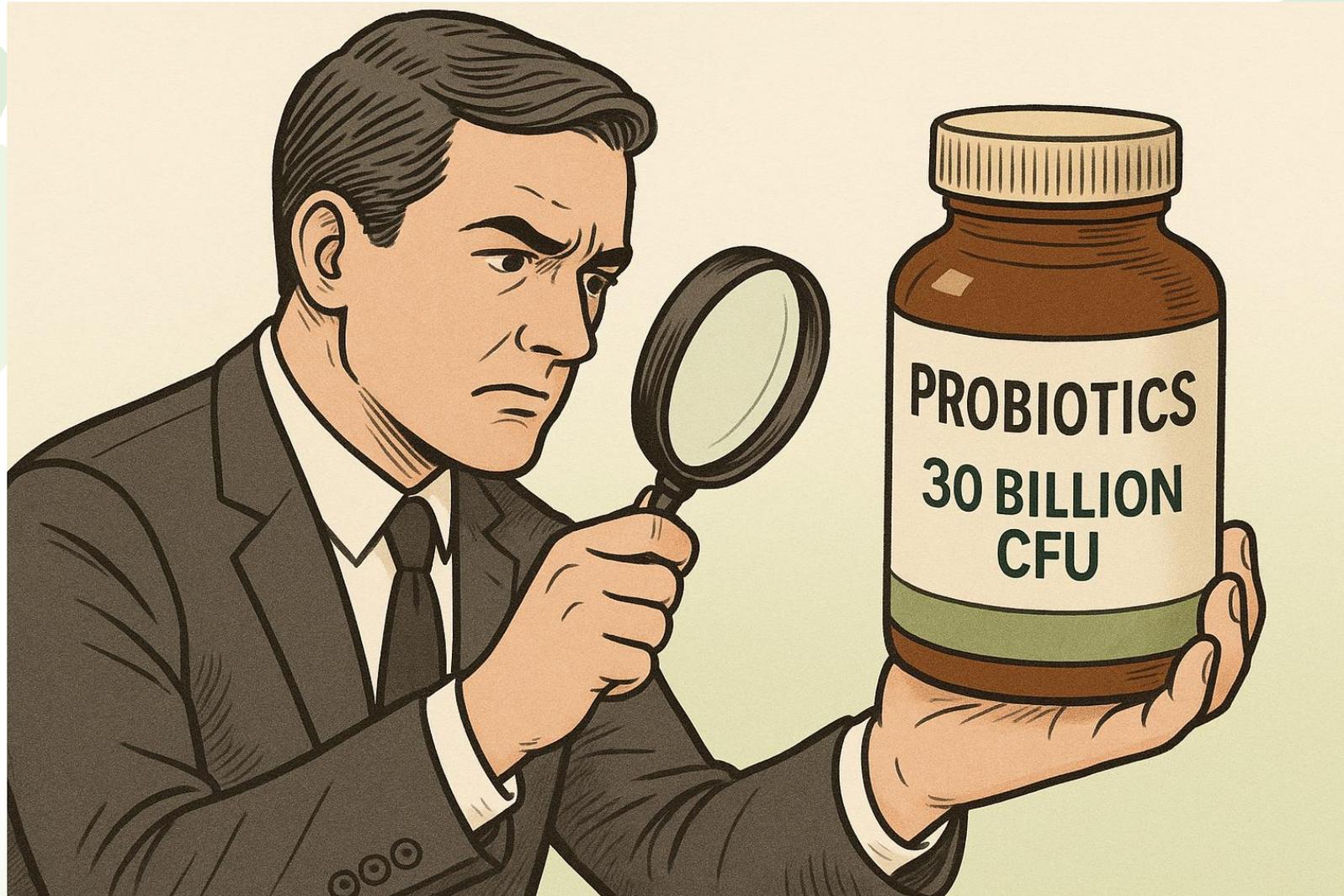


Therapy-Adjacent DO NOTS

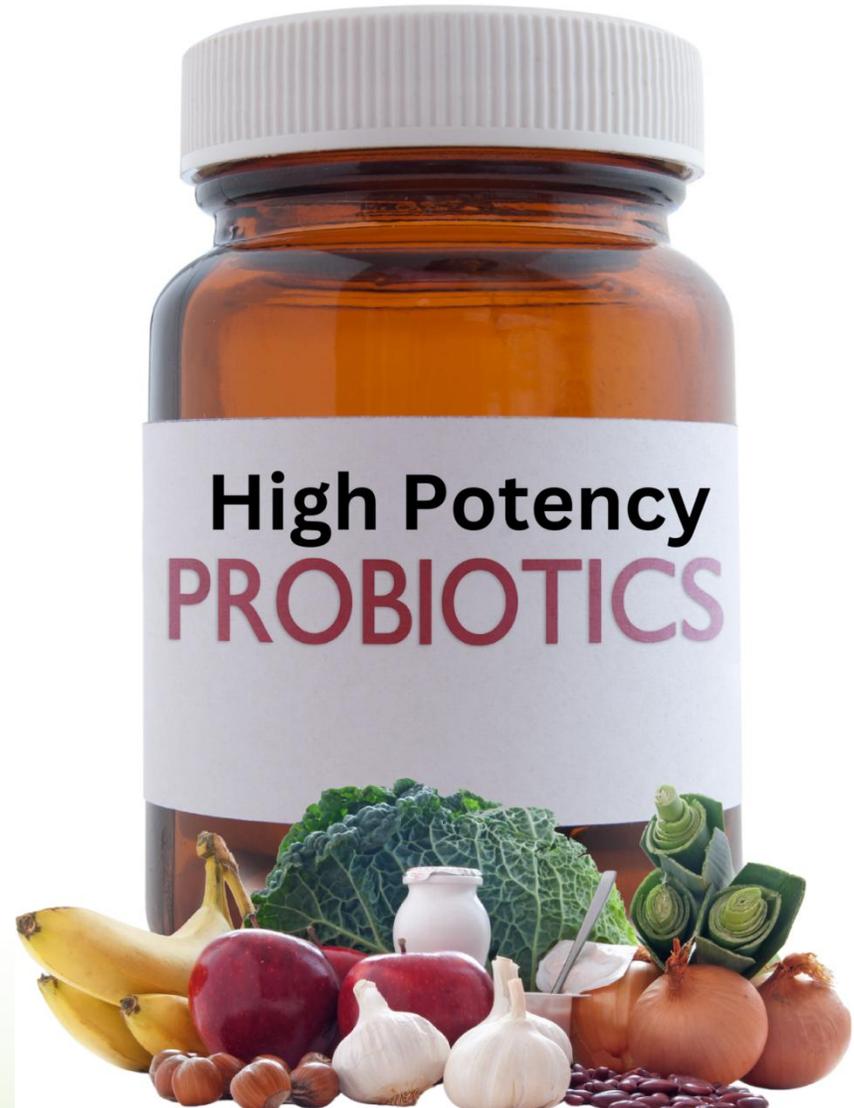
- ~~Take with antibiotics to prevent antibiotic-associated diarrhea~~
- ~~Helps reduce chemo or radiation side effects~~
- ~~Use with statins to prevent muscle pain~~

If you suggest your product augments a specific medical treatment, it will be regulated as a drug.

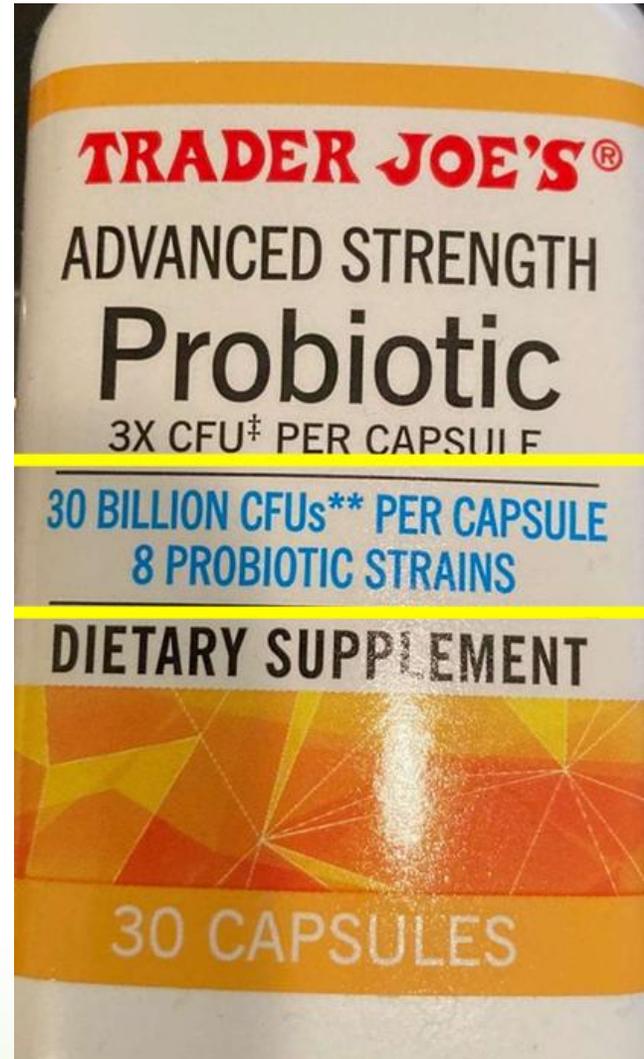
Label Claims



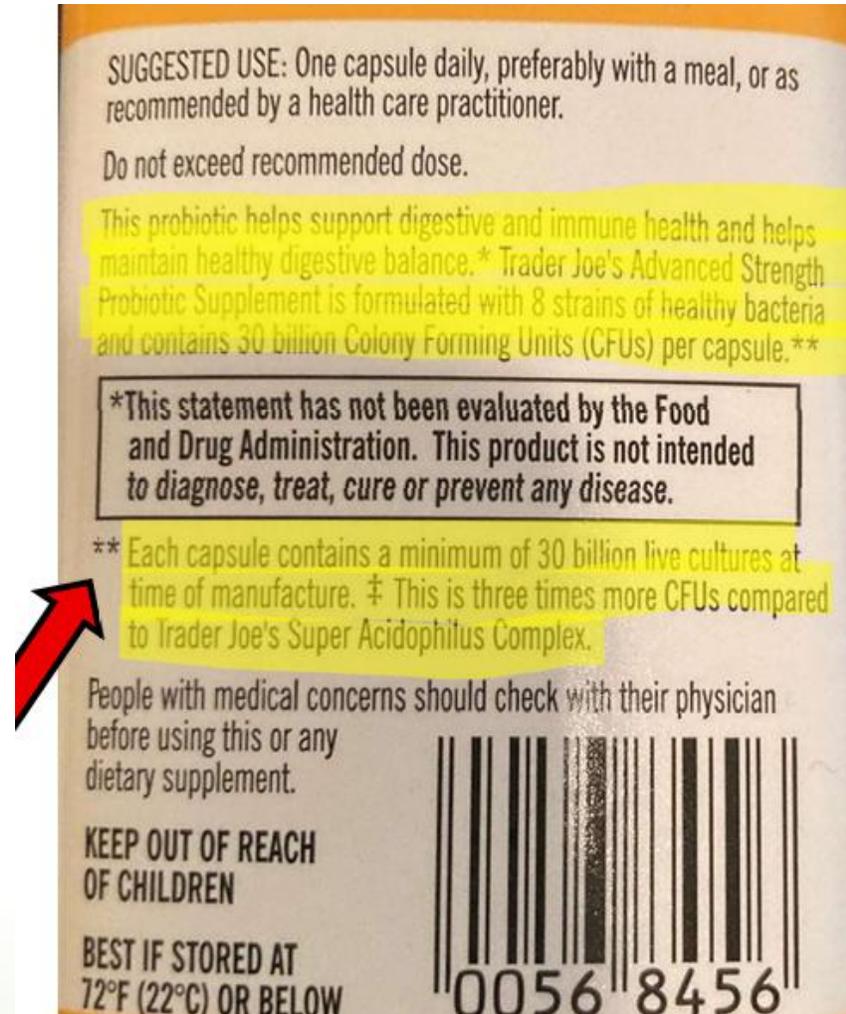
Nutrient Content Claims



CFU Labeling Litigation

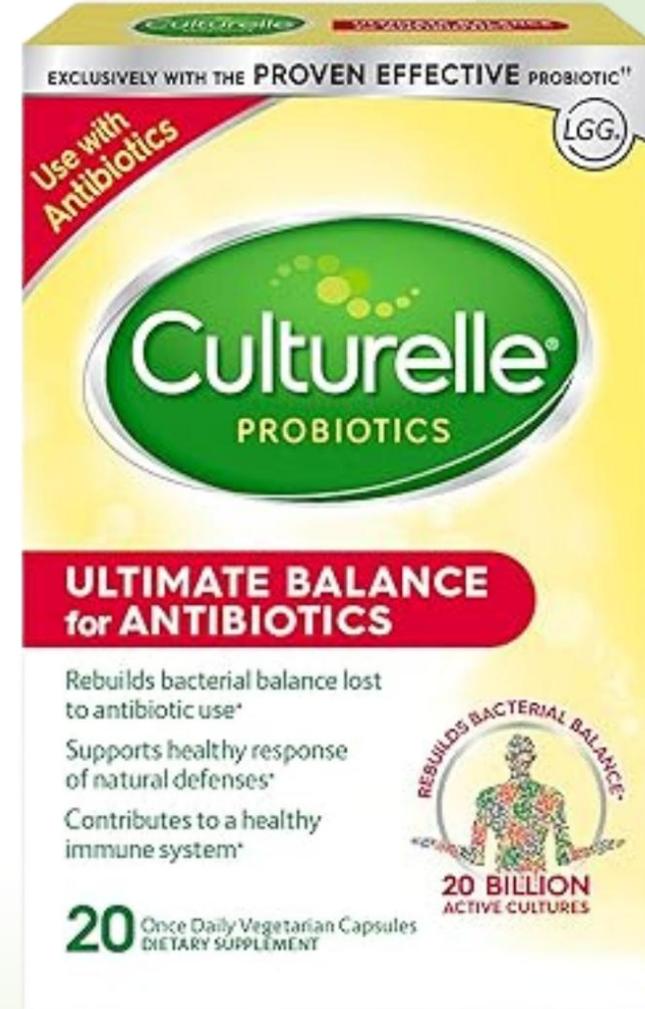


CFU Labeling Litigation



Culturelle Lawsuit

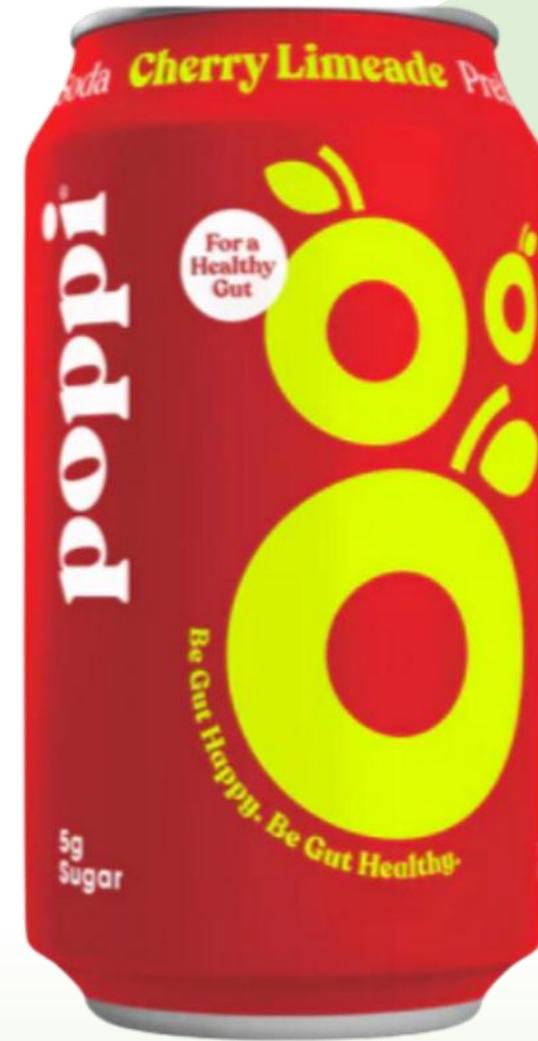
Lawsuit alleges “rebuilds bacterial balance lost to antibiotic use” is a disease claim.



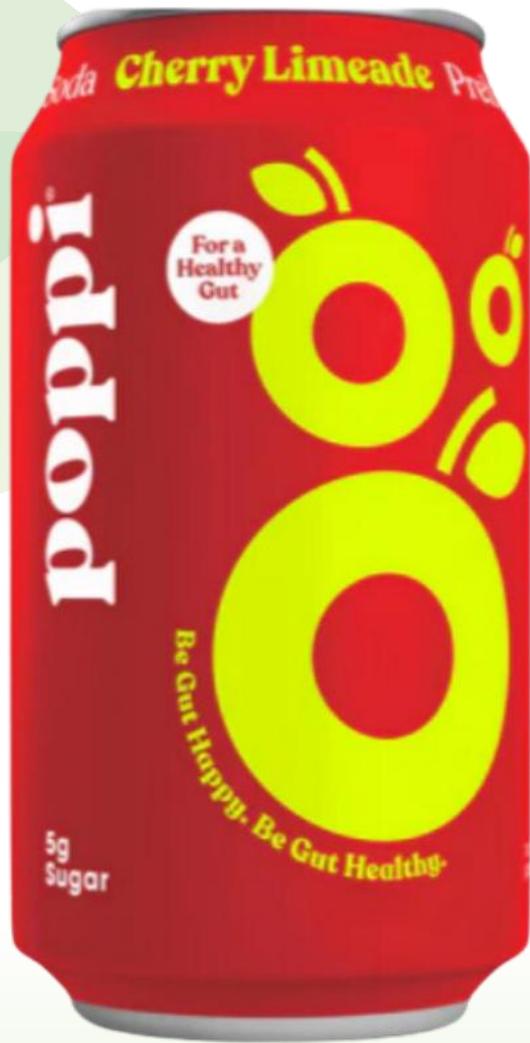
Prebiotic Claims Lawsuit

Lawsuit alleges that prebiotic levels are too low to justify the “healthy gut” claims

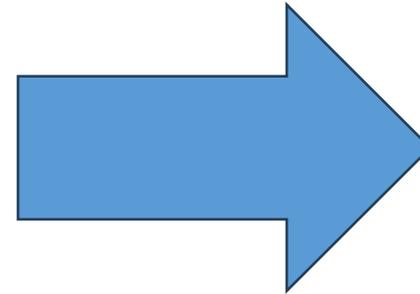
5 grams sugar may have counteracted digestive claims



Prebiotic Claims Lawsuit

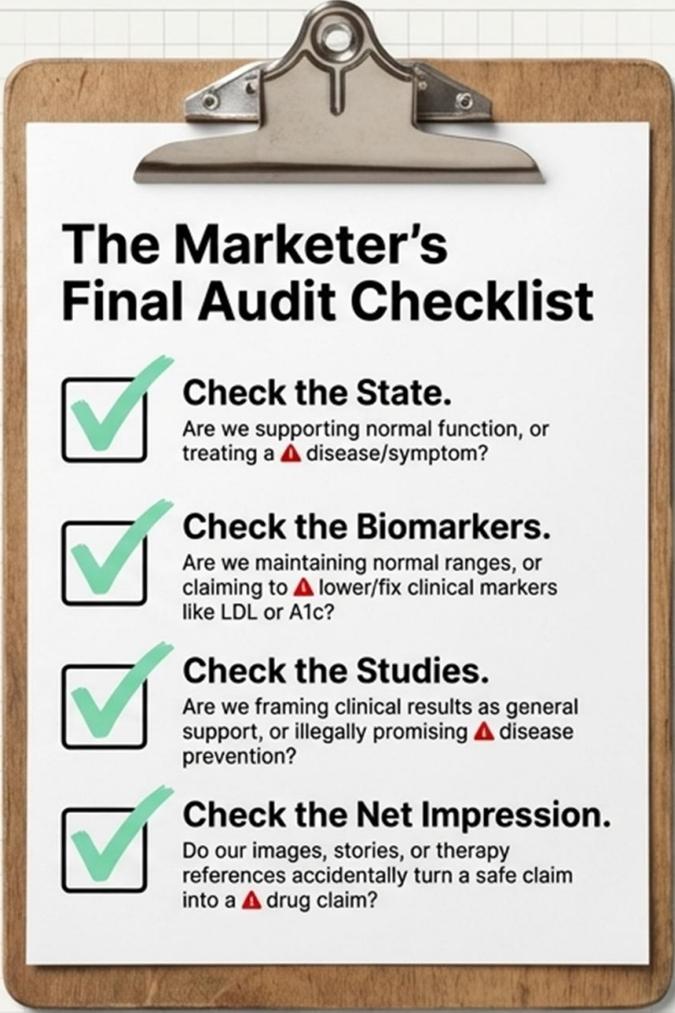


New Label



Cosmetic Class Actions





The Marketer's Final Audit Checklist



Check the State.

Are we supporting normal function, or treating a **Δ** disease/symptom?



Check the Biomarkers.

Are we maintaining normal ranges, or claiming to **Δ** lower/fix clinical markers like LDL or A1c?



Check the Studies.

Are we framing clinical results as general support, or illegally promising **Δ** disease prevention?



Check the Net Impression.

Do our images, stories, or therapy references accidentally turn a safe claim into a **Δ** drug claim?

Thank You



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