



Supplement Advisory Group



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COMPLIANCE

Clinical Studies to “Made in USA”: Marketing Branded Ingredients Without Stepping Over the Line

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Warning Letter Wednesday

Free Resource



271 Weeks!

August 27, 2025



Essential Make Claims

Takeaway - Top 10 weirdest and craziest claims ever seen. FDA issued a warning letter to a company selling an essential oil diffuser for Alzheimer's treatment, dementia, and other... makes them easier to substantiate



Unallowable Ingredient "Enough" to Trigger Regulatory Action

Takeaway - Delta-8 is a high-risk ingredient

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.

Substantiation is Important

- FDA
- FTC: Truth in advertising
- NAD
 - Challenges
 - Monitoring case
- Plaintiff's Bar
- Retailers/Advertisers: Amazon, Whole Foods



B2B Ingredient Marketing: Lower Visibility Does Not Mean Risk

- Supplier research and marketing materials can shape the claims that finished-product brands make to consumers.
- FTC substantiation principles apply to health-product marketing, including implied claims and “clinically proven” messaging.
- SupplySide applies its own compliance rules to ingredient descriptions, booth materials, websites, videos, and other materials presented at the show.

Practical goal: give customers strong science + retail-friendly claims they can actually use

The Study Should Match the Claim



Several important factors when ensuring claims are “okay”

Diseased Populations: Useful Science but Harder Marketing



FEDERAL TRADE
COMMISSION

Health Products Compliance Guidance

Example 34:

A number of well-controlled clinical studies have been conducted to suggest that a tea improves mental alertness in subjects with significantly impaired blood circulation to the brain. A claim suggesting that the tea will improve mental alertness in healthy adults isn't adequately substantiated by this evidence. Advertisers shouldn't rely on research based on a specific test population for claims targeting the general population without first making sure it is scientifically sound to make such extrapolations.

Diseased Populations: Useful Science but Harder Marketing

Ashwagandha study: subjects with subclinical hypothyroidism

- 50 subjects with elevated TSH; 600 mg/day for 8 weeks.
- Primary efficacy variables included TSH, T₃ and T₄.
- This study does not automatically substantiate a healthy-thyroid claim for the general population. Treatment claims raise a separate regulatory issue.
- **The study can strengthen a scientific dossier**, but the population and endpoints are explicitly disease-adjacent.

FTC principle: do not extrapolate from a specific test population to a different marketing population without a sound scientific basis.

Biomarkers: What Does the Claim Imply?

Cortisol

Useful in a stress story

Context matters; avoid turning a stress biomarker into an unsupported medical/endocrine promise.

Cholesterol

Classic FDA warning letter example

"Reduces cholesterol" is treated as an implied disease claim; "maintains cholesterol already in the normal range" is different.

CTX-II

Interesting joint biomarker

Often better used as substantiation than as a consumer headline unless the consumer meaning is clear and supported.

Biomarkers are risky, especially those related to heart disease and blood sugar

Biomarker Claims Enforcement

BergaMet North America LLC, FDA Warning Letter

- BergaMet Cholesterol Command is clinically proven to improve cholesterol levels. It reduces LDL

Essential Elements, FDA Warning Letter

- Vitamin B3, red yeast rice, and pine bark extract [ingredients in CholestAid] supply a natural way to help your body lower bad cholesterol levels



BioDrive EV1 Peptide: Case Study

FDA Warning Letter: BioDrive, Inc. — August 24, 2026

EV1-Peptide

1

Used in Evolv
GLP-1
Biomimetic

Two NDINs

2

Company
submitted two new
dietary ingredient
notifications

FDA objections

3

FDA said the safety
information was
inadequate and cited
potential toxicity
concerns

Product marketed

4

FDA says the
product was
marketed despite
those objections

Warning letter

5

FDA deemed the
supplement adulterated
based on inadequate
safety information

Important nuance: This warning letter focuses on NDI safety and adulteration. FDA's description of EV1 as a dietary ingredient is not an approval or endorsement of its safety, efficacy, or marketing claims.

B2B Has Another Compliance Filter: The Trade Show

SupplySide: “All materials displayed at SupplySide events are subject to the Compliance Program”

- Booth displays, package inserts, ingredient descriptions, promotional materials, websites, videos and other show content are covered.
- Disease claims are prohibited for dietary supplements, and statements must be substantiated.
- Onsite corrections may include removing materials or redacting / blacking out claims.
- Unresolved compliance issues may result in a standards hold and affect future booth reservations.

Retail-friendly claims do two jobs: they help customers market responsibly — and they help your booth survive compliance review.

Ingredient Supplier Enforcement Example

GCA® green coffee extract | FTC settlement, 2014

- FTC's complaint focused on GCA® green coffee extract, an ingredient used in dietary supplements and foods.
- The complaint says AFS sold GCA products to producers of finished supplements and foods.
- FTC alleged AFS sponsored a flawed clinical trial and then shared unsupported weight-loss claims with trade customers.
- FTC also alleged those materials gave customers the “means and instrumentalities” to repeat the claims downstream.

B2B marketing is not outside FTC's reach.

AFS also marketed a finished retail coffee brand. This case addressed its GCA ingredient marketing and materials supplied to trade customers.

NAD Decision

Cited in Class Action Complaint

- NAD Case: National Advertising Division Recommends Goli Nutrition Modify or Discontinue Various Claims for Ashwagandha Gummies

Weight Loss and Weight Management Claims

After considering the evidence provided by the advertiser to determine if it had provided competent and reliable scientific evidence to support claims that the ingredients in Ashwagandha Gummies are clinically proven to provide weight loss and weight management benefits, NAD concluded that the advertiser had not provided sufficient competent and reliable scientific evidence to support its claims.

NAD expressed concern with several methodological flaws in the advertiser's study on KSM-66 Ashwagandha that undermined the reliability of the results. NAD also found the results of this study, and the advertiser's vitamin D studies, to be a poor fit for the challenged weight loss and weight maintenance claims.

Therefore, NAD recommended that Goli discontinue the establishment claims:

- "KSM-66[®] Ashwagandha, plus vitamin D are clinically proven to help support weight management."
- "KSM-66[®] Ashwagandha has been clinically proven to...Reduce and maintain healthy body weight."
- "Research shows that by lowering cortisol levels, KSM-66[®] Ashwagandha can help reduce stress-related food cravings and weight gain."

Match claims to the study population and demonstrated benefits. Ensure other factors that could influence outcomes are accounted for

NAD reviewed Goli's advertising. KSM-66 manufacturer Ixoreal Biomed was not a party to the proceeding.

NAD summary: May 25, 2022. Caputo complaint: September 9, 2022, ¶¶39–41.

Country of Origin Claims

This is partially regulated by Customs, partially by FTC.

An unqualified "Made in USA" claim requires the product to be all or virtually all U.S.-made. Final processing and all significant processing must occur in the U.S., with all or virtually all ingredients or components made and sourced here.

The FTC has a guidebook on this.

Given the global economy, it's best to qualify these claims or avoid them entirely. (when suitable)

A flag or other emblem / trade names can also be problematic "Norwegian Cod"

Place of Origin Lawsuits

Not as explicit as “Country of Origin” claims

These are statements that might imply or confuse consumers as to the origin of the product

A 2022 proposed class action alleged that “Naturally French” misleadingly conveyed French manufacture. This describes the plaintiff’s allegations, not a court finding.



The Branded Ingredient **Supplier Playbook**

1

Design rigorous research to test the intended benefit

Healthy target populations and marketable endpoints make later translation much easier.

2

Build an approved claims matrix

Give customers “use / use with caution / do not use” language — not just clinical-paper PDFs.

3

Separate science from headline language

Disease-population data and biomarkers can stay in the scientific dossier without becoming retail copy.

4

Review the whole net impression

Study titles, charts, testimonials, images, GLP-1 references and U.S. imagery all matter.

5

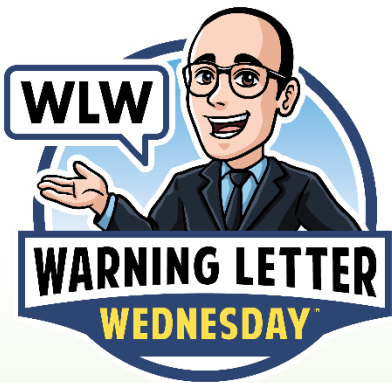
Keep sourcing + substantiation current

Claims can become inaccurate when suppliers, formulations, doses or country of origin change.

Best outcome: credible science that your customer can market without having to “translate around” the study



Thank You



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