



Supplement Advisory Group

# Active Aging Mastering the Market

Regulatory Enforcement Update:  
Making Your (Compliant) Message Shine

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Supplement Advisory Group

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## 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.



## Biomarker Warning Letters





## Discussing Ingredient Benefits Are Marketing Claims

Essential Nutrients, FDA Warning Letter

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



## Product Names Are Marketing Claims

iwi FDA Warning Letter

- "The product's name (iwi Cholesterol) is an implied claim that it reduces cholesterol."



## Testimonials & Product Reviews Can Be Claims



BergaMet North America LLC LLC, FDA Warning Letter

- On your testimonial page  
"Love Cholesterol Command! My ldl is down 28 points, my doctor was extremely surprised because I am allergic to statins so working on my cholesterol levels has been difficult until I found out about BergaMet ... haven't seen my cholesterol this low in 15 years"



## Videos Are Claims



### YouTube Videos Cited in Warning Letters

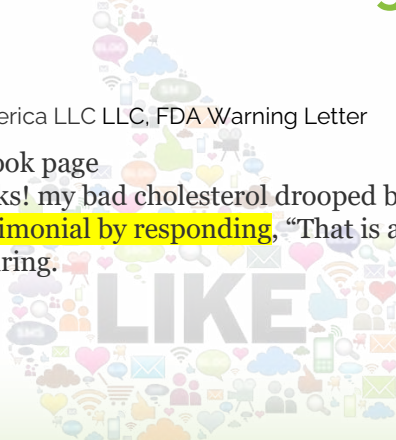
Healthy Trends Worldwide LLC, FDA Warning Letter

- On your YouTube video
- (2:57-3:08) "Now next is Hawthorn Berry [an ingredient in your BPS-5 product]. Used in traditional Chinese medicine for thousands of years, Hawthorn Berry is a popular ingredient used to fight back against blood pressure, blood disorders, and heart disease."

## “Liking” A Post is Endorsing the Claim

BergaMet North America LLC LLC, FDA Warning Letter

- On your Facebook page  
“Yes, it really works! my bad cholesterol drooped by 60 pts . . .” You endorsed this testimonial by responding, “That is amazing Jon! Thank you for sharing.”



## Common Marketing Mistake

### Using clinical verbiage to describe products

Desert Alchemist FDA Warning Letter

- “Happy Heart is a blend composed of mushrooms Known for . . . Cholesterol control, increases oxygen uptake, hypertension”
- “Fortify is an extract made from mushrooms with the best . . . immuno-modulating, antiviral, anti-fungal, and anti-bacterial properties.”



# How To Talk About Ingredient Research

Branded ingredient research may not = compliant marketing

## PREMIER JOINT SUPPORT SOLUTION WITH CLINICALLY PROVEN FORMULA

Randomized, Double-blind, Placebo-controlled Study  
(ClinicalTrials.gov Identifier: NCT04395547)

Subjects: 72 elderly with mild and moderate knee osteoarthritis, 40-75 years  
Intake: JointAlive® 600 mg/day or placebo  
Intake period: 12 weeks  
Primary outcome measures: change in knee joint function, pain & stiffness



# How To Talk About Ingredient Research

Be truthful and not misleading  
→ without disease words

- Pain Score (WOMAC) → WOMAC Scale
- Osteoporosis → Bone support
- Clinically proven → Clinically tested





## Cognitive Function FDA Claims Enforcement

- ✓ “Improved cognitive function” + “Parkinson’s” = warning letter

• “In fascinating **Parkinson’s** disease pre-clinical research modeling, Acetyl-L-Carnitine improved cognitive function, extended neuronal survival and modulated key imbalances between cytokines.”



## “Brain Boost” Class Action

*Marietta Viera et al., v. Ancient Brands LLC, Case No. 1:23-cv-02242*

- According to the lawsuit, Ancient Nutrition sells a “Multi-Collagen Protein, Brain Boost” product that it purports is scientifically studied and is proven to be “brain-boosting.”
- According to the lawsuit, none of the ingredients in the product are scientifically proven to improve cognitive function.

# Brain Performance –vs – Brain Health

Neuriva Class Action (Williams, et al. v. Reckitt Benckiser LLC, et al.)



# Is “Brain Fog” a Claim



## Is “Brain Fog” a Claim

COVID related “brain fog” can be considered a disability under ADA laws.

- “Brain fog” is a symptom of COVID
- From HHS guidance on long haul symptoms

A person with long COVID who experiences memory lapses and “brain fog” is substantially limited in brain function, concentrating, and/or thinking.

## “Libido” Claims Are Risky

- ✔ Amazon will require increased testing
- ✔ Invites increased regulatory scrutiny
- ✔ Test product to ensure no adulteration



## Eye Health Claims Enforcement

*New Sun Inc. FDA Warning Letter*

"Eyebright has been traditionally used to treat all manner of eye maladies including; inflammation, **conjunctivitis**, red-eye, sties, itchy eyes, stinging eyes, and weak vision."



## Class Action News: Joint Support Claims

### Joint Juice Lawsuit

From the lawsuit:

- *Defendant promises that Joint Juice will support and nourish cartilage, lubricate joints, and improve joint comfort.*
- *Joint Juice helps to support and nourish cartilage, "lubricate" joints, and improve joint comfort*



## NAD Case: Joint & Muscle Claims

### Claims made by direct sales affiliates Prime My Body



## Bone Health Enforcement

FDA: Focusing on osteoporosis claims

AZ Pharmaceutical, Inc, FDA Warning Letter

- “Some studies have found that vitamin D can actually slow down bone loss, warding off osteoporosis and keeping you stronger for longer.”

## Arthritis Claims Top of Mind for FDA

10 FDA Warning Letter Mentions This Year

- Most common “itis” in warning letters



## FTC Enforcement Joint Health Claims

FTC Order to Bar ZyCal Bioceticals from Deceptive Health Marketing

Company claimed its product could grow bone and cartilage, relieve joint pain



# Thank You



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