



Supplement Advisory Group

Active Aging Mastering the Market

Regulatory Enforcement Update:

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Supplement Advisory Group

Asa Waldstein

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- o American Herbal Products Association (AHPA)
 - o Cannabis Committee Chair
- o 20+ Years Manufacturing/Marketing Supplements
- o 3 FDA Inspections: No 483's
- o Certified Clinical Herbalist
- o Warning Letter Wednesday: Weekly regulatory post



 Let's Connect



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.



FDA Sends Seven “Heart Health” Related **Warning Letters**



Discussing Ingredient Benefits Are Marketing Claims

Essential Nutrients, 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"

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



Eight FDA YouTube Letters This Year

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."

Product Names Are Marketing Claims

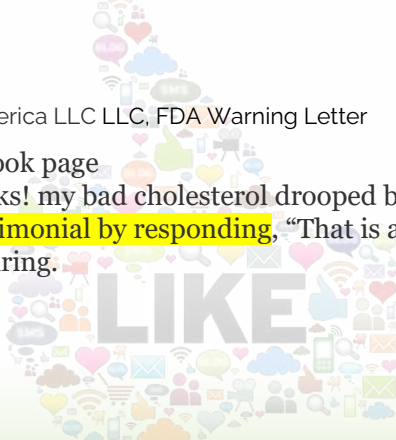
iwi FDA Warning Letter

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

“Liking” A Post is Substantiation

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.”



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.”



Arthritis Claims Top of Mind for FDA

30 FDA Warning Letter Mentions This Year

- Most common “*itis*” in warning letters



The Art of Wordsmithing

Make your point without high risk “buzzwords”

- Replace high-risk words like lower risk alternatives



Possible Alternatives to “Anti-inflammatory and Pain”

Be truthful and not misleading

- Discomfort
- Recover
- Relief or Soothe

Common Blogger Trap

Example: *Tips For Joint Support*

- ✔ Describe the cause of joint issues such as using disease words such as arthritis
- ✔ Natural therapies such as meditation and hiking
- ✔ Ingredients or products that can help.



This implies that products sold on the website can help with depression
Risk is elevated with hyperlinks

Risks Making “Libido” Claims

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

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Possible Alternatives to "Hair Loss Prevention"

Be truthful and not misleading

- Supports healthy hair
- Supports hair growth
- Healthy follicles help grow healthy hair
- Formulated with biotin for healthy hair

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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."

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NAD Enforcement: Anti Aging Company

NAD Case: Root Wellness LLC, a/k/a Root Brands



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*



Thank You



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