



Supplement Advisory Group

MICROBIOME

MASTERING THE MARKET

Regulatory Update:
Enforcement trends, risks, and best practices for
manufacturers & marketers

Asa Waldstein

Principal, Supplement Advisory Group

Legal Disclaimer

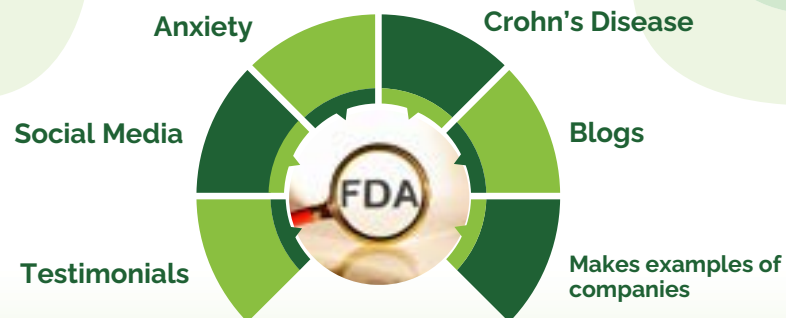


- This presentation consists of general information. It is intended for general education only.
- Due to the importance of individual facts of every situation, the generalization in this presentation may not necessarily be applicable to all situations. Changes in the law could make parts of this presentation 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 Claim?

- Anything ending in "itis" refers to inflammation-of, such as colitis
- Anything a drug is "indicated for," such as drugs being indicated for diarrhea
- Most things with "anti" in the name, such as anti-inflammatory
- The name of any disease or syndrome, such as Crohn's disease or IBS.

Why Do Some Companies Receive FDA/FTC Scrutiny?



Warning Letters Lead To Class Actions

- **FDA/FTC Warning Letters**
 - Alerts class action attorneys
- **NAD Decisions**
- **Product Recalls**



Is “Leaky Gut” a 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."

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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

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“IBS” Symptomatic Support = Claim

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

On your product description page:

- “Designed to relieve Irritable Bowel Syndrome (IBS) symptoms including diarrhea and constipation”
- “Reduced, . abdominal pain”

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Gut-Brain Claims

Make your point without high risk “buzzwords”

- Balanced state of mind, happy mood support, supporting you in the overwhelming moments
- Healthy microbiome = mental clarity
- Clear-minded and ready to focus on those important projects.
- *A healthy digestive system helps support a positive state of mind*

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“Better Than Drugs” Statements = Risky

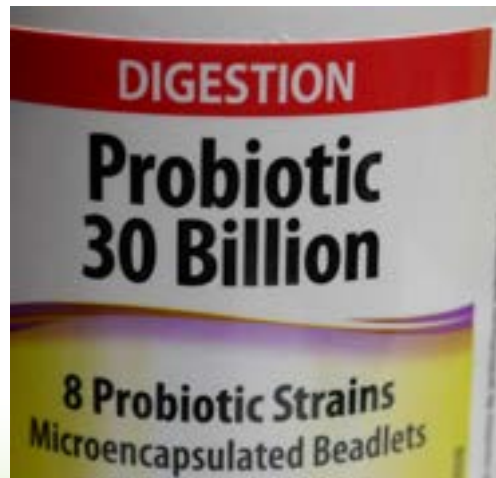
FDA Warning Letter: JLM Nutritionals, Inc. dba JLM Nutrition—Super Naturals Health

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

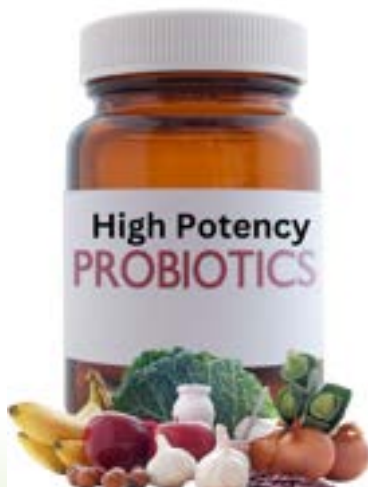
• “On 04/25/16, Jordyn in Los Angeles wrote: . . . I have been suffering for about a year now with IBS-D. . . . I was then diagnosed with IBS-D. I had no idea that IBS could be so debilitating. . . . Luckily I found IBS Formula! **I have been off my medications and on this formula for a month.** An entire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

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Label Claims

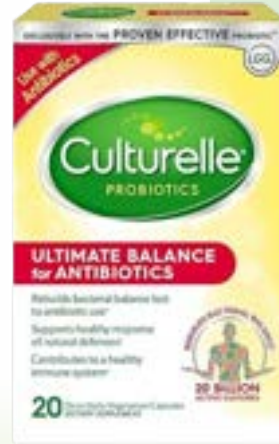


Nutrient Content Claims



Culturelle Lawsuit

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



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Prebiotic Claims Lawsuit

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



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Clinically Proven = Highest regulatory scrutiny

NAD Challenge Case: "Culturelle" Probiotic

NAD noted in its decision that the use of the terms "most clinically proven effective" and "#1 clinically proven effective" indicate to consumers that there is scientific evidence that proves or "establishes" the truth of the advertiser's claim.

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Class Actions

The NextFoods GoodBelly Probiotic JuiceDrinks Class Action Lawsuit is *Andrade-Heymsfield v. NextFoods, Inc.*, Case No. 3:21-cv-01446-BTM-MSB, in the U.S. District Court for the Southern District of California.



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The lawsuit alleges misleading marketing claims

“START YOUR GOODHEALTH GAME PLAN . . . Drink one 8 oz. glass of delicious GoodBelly a day for 12 days.”

“Reboot your belly, then make GoodBelly your daily drink to keep your GoodHealth going. Because when your belly smiles the rest of you does too.”

“WE DIG SCIENCE. LP299V is naturally occurring in the human gut. It has been studied more than 2 decades and has numerous research trials to show that it may help promote healthy digestion and overall wellness”

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Cosmetic Class Actions



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Thank You



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