



Supplement Advisory Group

MICROBIOME

MASTERING THE MARKET

Regulatory Update:

**Enforcement trends, risks, and best practices for
manufacturers & marketers**

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- Principal: Supplement Advisory Group
- Founder: Asa's Regulatory Education Series
- American Herbal Products Association (AHPA)
 - Cannabis Committee Chair
- 20+ Years Manufacturing/Marketing Supplements
- 3 FDA Inspections: No 483's
- Certified Clinical Herbalist
- 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.



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, such as Crohn’s disease
- Am I making a statement that can be construed as treating, diagnosing, preventing, or curing any disease?



What Are Repercussions of Not Complying?

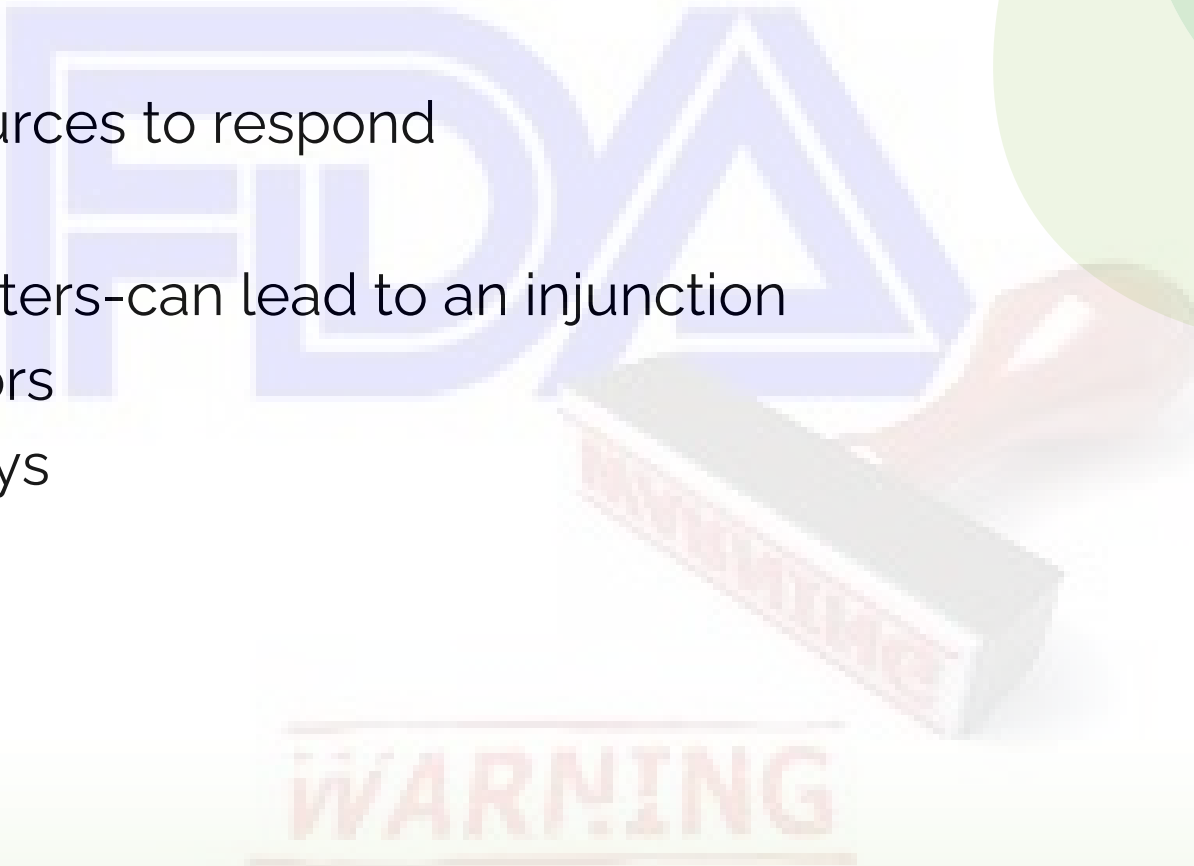
- **Warning Letter**

- Requires legal resources to respond
- Public record
- Repeat Warning Letters-can lead to an injunction
- Scares away investors
- Class action attorneys

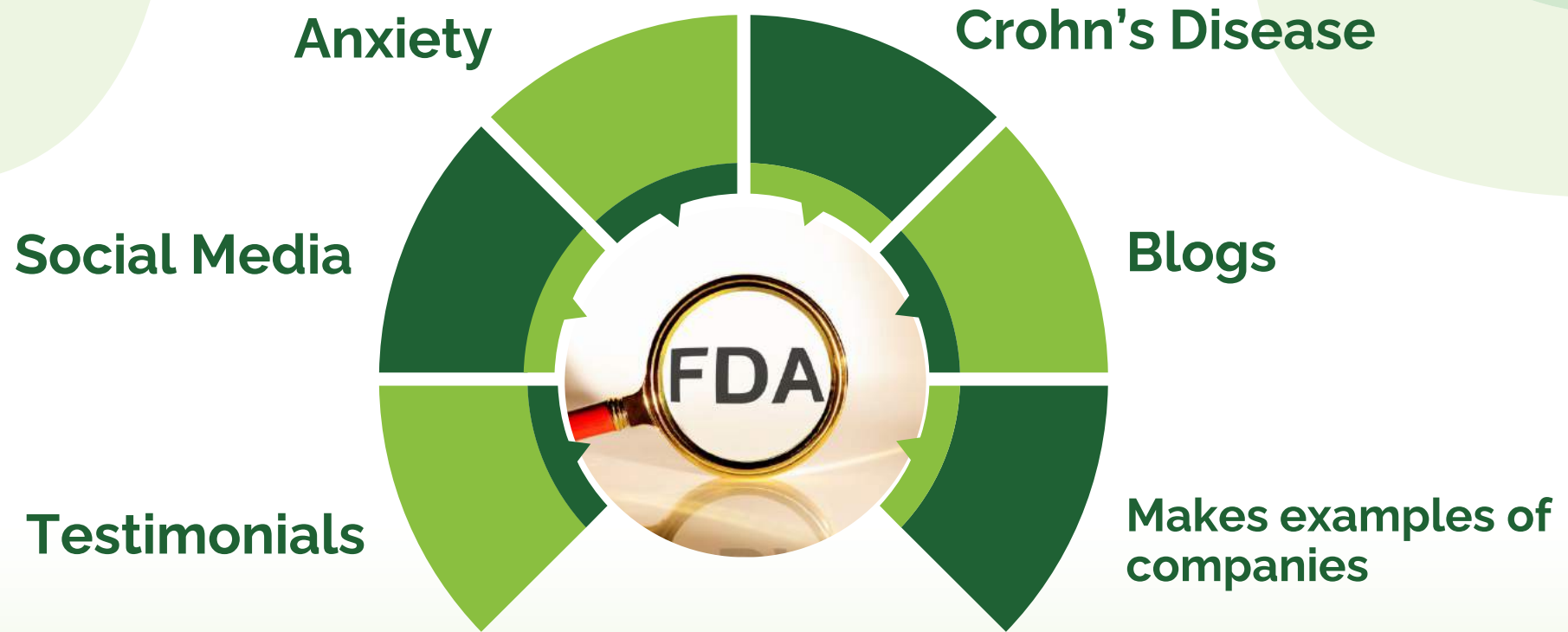
- **Class Action Lawsuits**

- **NAD Cases**

- **Poor Public Perception**



Why Do Some Companies Receive FDA/FTC Scrutiny?





Key Enforcement Trends

- Blogs
- LinkedIn
- Product & Meta tags
- Testimonials
- Citing Clinical Studies
- Hashtags





Hashtags are Claims

- A normally compliant post can be made non-compliant with the use of a hashtag



#ProbioticsForCancer
#NoMoreIFD

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.”

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



Implied Covid Claims= High risk

FTC Warning Letter: JB7, LLC

COVID-19 AND GUT MICROBIOTA

Microorganisms in the gut may help identify who is at risk of complications from Covid-19, including severe illness and inflammation. What's striking is that even after recovery, gut microbiota can remain altered and patients can continue showing symptoms like fatigue, dyspnea, and joint pain....

In other words: A leaky gut triggered by an unbalanced gut microbiome allows the virus to leak into the circulatory system, making it easy to spread across organs....



Is “IBS” a Claim





“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”



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*



“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."



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.

Marketing Differences Supplement & Clinical Study Words

Be careful using clinical study terminology
to describe products

Anti-inflammatory	➡	Soothing
Anxiety	➡	Mood Support
Insomnia	➡	Sleep support
Antiemetic	➡	Stomach soothing



FTC Action





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.





GoodBelly PROBIOTICS
is a delicious blend of fruit juices and a daily dose of probiotic cultures created to naturally renew your digestive health, right where your overall health gets started — in your belly.

Probiotic Supplement
problems

12 DAY Belly Reboot

START YOUR GOODHEALTH GAME PLAN

- 1 Sign up at: goodbelly.com/12-day-reboot
- 2 Check your email for coupons and print 'em out.
- 3 Drink one 8 oz. glass of delicious GoodBelly a day for 12 days. (That's just 3 cartons worth.)
- 4 We guarantee you'll love it — or your money back.*

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.

* Some restrictions apply.

Why Probiotics?

When microflora in the gut gets out of balance, harmful bacteria may take over and may cause:

- Cramping
- Diarrhea
- Fistulace
- Constipation
- Bloating
- Fatigue

Why GoodBelly?

PROBIOTICS IS ALL WE DO!

WE WALK THE TALK: Our strain, LP299V, has been recognized as one of the most researched and impactful probiotic strains available.

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

When in **BALANCE** the intestinal microflora:

- Supports healthy digestion.*
- Promotes regularity
- Aids in absorption of nutrients.

→ Experience GoodBelly for yourself. Getting your probiotics is now easy and delicious!

Feel Your Belly Smile

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”

Cosmetic Class Actions





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Thank You



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