

Speaker 1 ([00:00](#)):

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Justin Prochnow ([00:26](#)):

Hello and welcome to Legal Food Talk. I'm your host, Justin Prochnow, a shareholder in the Denver office of the International law firm, Greenberg Traurig. This is a podcast brought to you by our food, beverage and agribusiness practice to give you some insights and knowledge about the world of food, beverage and agribusiness.

([00:55](#)):

Hello and welcome to another edition of Greenberg Traurig's Legal Food Talk. Today I'm manning the booth by myself, and we're going to be talking about some advertising today. I was just out in Las Vegas for the Affiliate Marketers Summit, Affiliate Summit West, where we had about five or 6,000 affiliate marketers getting together to talk about advertising. Now, you're probably familiar with some of these advertisements that you see on the internet that you click on.

([01:33](#)):

Sometimes they have a fairly long kind of advertisements, and I joke around a little bit that you know, you'll read one and it'll say something like, "I am about to tell you about the most amazing discovery I've ever had. But before I tell you about that, let me tell you about how I got there. I used to weigh 450 pounds, and I was unhappy with my life, but I went into this shop one day and the old man there told me about this mountain village in the Himalayas where everyone lives to be 130 and weighs a hundred pounds. And he told me about the most magnificent ingredient you've ever heard of. But before I tell you about that ingredient, let me tell you about a few other things." And you're trying to fast forward through that ad or rewind, and you can't do it because they want you to stick around for the whole thing. When you get to the end of it, the most amazing ingredient is ginger or green tea, something.

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Those are obviously extreme ads, but we work with a lot of companies both doing extreme ads as well as the day-to-day ads. Of course, fundamentally to all of those is needing to be compliant with the rules and laws regarding advertising. So when I was out at Affiliate Summit West, did a little presentation for one of our clients, the Supplement Millionaire. We talked about the top 10 things on the radar for the FTC and the FDA for advertising in 2023. Everyone loves the top 10 list, going back to David Letterman and his top 10 list of all sorts of favorite things. So today we're going to give you the top 10 things to think about as you're advertising in 2023.

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Before we get going, it's important again to understand the interplay between the FDA and the FTC when regulating claims, and we've talked about this before in some of our other podcasts where we've talked about weight loss claims or immunity claims during COVID. But there's really two main federal agencies that regulate advertising for food, beverage, dietary supplement, cosmetic products, and that's the FDA and the FTC. The FDA, as we know, the US Food and Drug Administration regulates labeling, which is things that are on the label of your product or other written, printed or graphic material that accompanies your labels. The FDA has primary jurisdiction over your labeling.

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Fundamentally, the FDA looks at your labeling to decide whether you are making appropriate claims for the type of product that you have. So for a non-drug product, as we know, and we'll talk about it later, you've heard me say it many times, you cannot sell a non-drug product to diagnose, treat, cure, or prevent the disease. Fundamentally, that's what the FDA is looking at when they're reviewing your labeling.

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The Federal Trade Commission, the FTC on the other hand, looks at advertising to determine whether claims are truthful and not misleading, whether they're fair and whether they're properly substantiated. Now, we always want to be compliant with both the FDA and the FTC. Companies should want to be good corporate citizens. But the reality is the FDA, unless you're making an inherently unsafe product, is probably going to give you a couple bites at the apple.

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Generally, they might send you a warning letter, an inspection and tell you, "Hey, don't do that anymore." As long as you change it, you're going to be okay. The FTC is really the 900-pound gorilla in the room. By the time the FTC gets to you, it's often too late because they've already investigated it. They've looked at it. They've talked to other people. By the time you get a civil investigative demand, a CID from the FTC, they're already far down the road. So we want to make ultra sure that we're careful both from an FDA perspective, but especially from an FTC perspective. Of course, we also have our friends, the class action plaintiff lawyers. We're not going to give them a lot of time and energy today because they sap too much of our time and energy the rest of the time.

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So we're going to start with the number one item that companies should be aware of, and it's something that the FTC looks very closely at. That's whether you have substantiation for your claims. Lack of substantiation is really the biggest risk of action from the Federal Trade Commission as well as some of the complimentary organizations, the National Advertising Division of the Better Business Bureau, which is really a nonprofit self regulatory agency for industry that evaluates certain types of claims and allows competitors to challenge claims and then state attorneys general offices who have members that go around looking for false and misleading advertising as well as responding to complaints from constituents.

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The general rule of thumb is that all health claims must be substantiated by a standard of competent and reliable scientific evidence. There's no statutory definition of what constitutes competent and reliable scientific evidence, but the standard defined by the FTC is tests, analyses, research, studies or other evidence that have been conducted and evaluated in an objective manner by qualified persons that are generally accepted in the profession to yield accurate and reliable results.

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So often when I'm speaking at presentations, I say that and then I looked around to see who actually has any better understanding of what that standard is now. Generally, there's not very many hands. It's a tough standard. What it essentially means is the standard is whatever the FTC decides on that particular occasion. The gold standard for a long time has been a double-blinded placebo controlled clinical trial on your product or formula. Most companies don't have the money to do a well-designed double-blinded placebo controlled clinical trial.

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So the next best is a study on one or more of the ingredients in your product. This is where I often see the biggest deficiency amongst companies when I'm evaluating their claims and their proposed substantiation for the claims is if you're making a claim about an ingredient like Ashwaganda or turmeric or ginger, it's not enough to just have a bunch of studies that suggest that Ashwaganda will help with focus and concentration or turmeric will help with post-exercise inflammation. You need to make sure that you have studies that support that the amount in your product will actually substantiate those claims. I often get substantiation sent to me from marketing departments and other areas where they say, "We have all sorts of studies on this." But when you actually go through them, there's very few studies that actually support the amount in the product.

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For a number of years, the FTC had a guidance. It was a green book, Advertising for Dietary Supplements. Most recently the FTC issued a revised guidance just before Christmas in December of 2022. It's called the Health Products Compliance Guidance. There were a lot of changes made to the previous dietary supplement guidance that was provided by FTC. One of the biggest changes in this guidance is that it now encompasses all sorts of health products, not just dietary supplements. So it's called the Health Products Compliance Guidance, and it really updates the previous brochure, which first came out in 1998. Amongst a number of factors, there's a big discussion on what the FTC evaluates when they're looking to determine whether substantiation is compliant or not. One of the clear things that has resulted from this new guidance is that the FTC really has moved towards thinking that the only reliable science is going to be a well-designed blinded placebo controlled clinical trial.

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In the past, the FTC had indicated that if there were not studies done on a particular ingredient in humans, that you could potentially rely on animal studies or in vitro studies or other forms of science. But it's clear from this guidance and from people who have evaluated this guidance after it's been released that the FTC is really trying to move to a standard of you have to have at least one clinical trial on your product or on ingredients in your product if you are really seeking to substantiate claims. So an important change in the philosophy, it's been moving that way. You've seen it in consent decrees and others, that the FTC has been leaning that way, but this guidance makes it even more clear that you really shouldn't believe that your claims are substantiated unless you have at least one clinical study in support of your claims.

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It's really important that you have this type of substantiation because the failure to have substantiation can lead to the Federal Trade Commission taking action through the Department of Justice and the US Attorney's Office. You are subject to discouragement of profits, sometimes criminal prosecution and a consent decree where you're under the thumb of the FTC for 10, sometimes 20 years. So you have to have science to back up claims. It's not enough to just have general science. You have to have science on the amounts of the ingredients in your products. It's really the number one issue for companies advertising about dietary supplements, food, beverages. You have to have the science to backup claims.

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Number two on our top 10 list is just the second part of FTC, which is false and misleading claims. A fundamental mantra of advertising is that it has to be truthful and not misleading. This is difficult in advertising because a lot of times you think about advertising and at the very least, it's made up to recreate stories. So this happens a lot as I was talking about in kind of the long form affiliate marketing things where there's a story created to sell the product. The FTC essentially said, "You can't. It's not that you can't make up a story, it's that you can't make up a story and have people think that it's true."

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So you need to include proper disclosures to indicate that this is a fictional recreation of something. Sometimes there's no amount of disclaimers that you can make that won't make it misleading, so you have to be very careful about this when you do it. Probably the best example of the FTC taking action in this area was action taken by the FTC about 10 years ago against a bunch of companies that were marketing acai berry weight loss products.

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It's funny when acai Barry first came on the scene, you could kind of tell the people who were familiar with the industry as opposed to outsiders because they would call it Akai berry. It's spelled A-C-A-I, acai. But unless you've seen it and heard about it before, it looks like Akai. So when you saw someone say "Akai" berry, you knew they were probably coming at this from not directly in the industry. But there was an action taken by the FTC against 10 affiliate marketers as well as the brand owners of this acai berry weight loss product.

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Essentially the FTC's case was based on the fact that these products were being promoted online through fictional news cast. So it would say something like, "Action 5 News has uncovered the weight loss cure." It would talk about how they had this female reporter who took the product for 30 days and lost this weight, and now they're bringing it to you. If you just click on this link, you'll be able to get the product.

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Well, of course, the whole thing was made up. There was no Action 5 News. There was no reporter. It was a stock photo from someone in France. The whole thing was made up and the FTC said, "This is misleading. It's false and misleading. There is no Action 5 News and took action against 10 of these affiliate marketers as well as the brand owner itself. So if you're going to do something like that, you have to make it very clear that in fact, this is a recreation or a paid advertisement for it. You see this on TV a lot too, where you'll turn on the TV on a Saturday afternoon, and there will be this show. It'll be like Health Now. It'll look like a news report with a studio and everything, and it'll be sitting there. Then they'll have this CEO of a company talking about their new dietary supplement product for weight loss or arthritis, and shouldn't be for arthritis because of course it's a dietary supplement.

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What's our number one rule? You can't sell dietary supplements to diagnose, treat, cure, prevent a disease, but for joint health or for any one of a number of different issues, and the whole thing's made up. There is no Health Now, it's a paid ad. That needs to be disclosed very clearly, "This is a paid advertisement for the company doing it." Even then there is risk that the FTC would say, "It's so false and misleading that you can't even disclose or disclaim your way out of it." So something to be very cognizant of when you're doing advertising, especially some of these long form advertising, if you are creating this whole story, you need to be very upfront and tell people, "This is a fictional story of how we came across this ingredient to get you to know about it." It's a tough situation because inherently what you are doing is not providing truthful misinformation or truthful or at least misleading information.

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So you need to properly disclose it so that there is no case for someone saying, "You're really being misleading by making me think this was something when it's not." If you're upfront and say, "Here's a

situation of how it might happen," or something like that, then you're probably going to be okay. It's a tricky one. So something to really pay attention to as you are creating those situations.

[\(17:18\)](#):

Number three, we're going to shift over to the FDA side of things, and I've talked about it already several times. Again, the number one mantra, you cannot sell non-drug products to diagnose, treat, cure, or prevent a disease. This is not an issue of having the science. You can have all the science in the world. Albert Einstein could do your clinical trial. You simply, congress has decided you can't make disease claims for non-drug products.

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From the FTC perspective on disease claims, the reality is that FTC, they are not evaluating where whether the claim that you are making is permissible for a drug product or not. What they are evaluating is do you have the science to back it up? Now, typically they're going to be more skeptical or apply more scrutiny to the science needed for disease claims than for non-disease claims because the general feeling is you would likely be selling it as a drug if you really have the science to support a disease claim. But they're not making the evaluation on whether that's actually a permissible claim for that type of product.

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We're still in the COVID area. The number one way to get action from the FDA and the FTC is to make COVID claims. A lot of times the FDA and the FTC can be accused of moving slow in some situations. They have not moved slow in the COVID era on making COVID claims. In particular, there has been an increased focus of late on brain fog related to COVID-19. So I would be especially on alert for any claims related to brain fog, whether you specifically mentioned COVID-19 or not. They are on the lookout for those types of claims, so can't be anymore clear, do not make COVID claims.

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If you've got evidence that supports that your product will help with COVID then you should file a new drug application, and everyone will be very happy once that gets approved. But until then, you're just not allowed to make claims regarding COVID. That really extends to anything related to any sort of virus or other sort of immunity disease right now are going to be looked at with very close scrutiny.

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We've had a previous podcast before. Check out our archives to see some of our other podcasts, but we've done one on weight loss products before. So I won't spend too much time on that here. But be rest assured, especially in the first three or four months of a year, the FTC is looking closer at weight loss products than it probably does the rest of the year. Of course, this is because everyone's New Year's resolution is to go out and exercise more, lose some weight. There's a lot of stats about how gym memberships jump up in the first couple months of the new year, even stats about how bars and things are a little bit lighter in January as everyone decides, "Oh, I'm not going to drink for a while." Then by the time February and March roll around, we start to see an uptick in that and a downtick in the ... Maybe an uptick in the gym membership cancellations. So weight loss products are always going to be a heavily scrutinized category, but even more so during the first part of the year.

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It's almost 10 years ago now. In 2014, the FTC famously initiated operation failed resolution in 2014. Starting off the year took action against four or five different products in a variety of areas, including a tea, a dietary supplement. There was some underwear that you could potentially wear and lose weight. They've taken action against magnets. They certainly have a healthy dose of skepticism for products that

make it seem too good to be true. Along with this, the FTC has issued something called the Gut Check, which is a reference guide for media and other advertisers on spotting weight loss claims.

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What the FTC basically says is if the advertising that you've been asked to put on your website or promote in other areas makes one of the following seven claims, you should do a gut check. You should really think about it as to whether that is a claim that seems too good to be true and either get some more information about it or not air that type of claim.

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So some of those are things like causing weight loss of two pounds or more a week for a month or more without dieting or exercising, causing substantial weight loss no matter what or how much the consumer eats. These two kind of go hand in hand. I mean, we've seen some big actions against companies. There was the action against Sensa a couple years ago, which was this magic powder that you would sprinkle on products, and you would lose a lot of weight. It allegedly had something to do with blocking your sense of smell and therefore, just causing you to not want to eat as much. When those ads first started, you saw ads with hamburgers dripping with cheese and pizza, pepperoni pizza and all sorts of food. You can eat as much as you want. You don't have to exercise, you just sprinkle this on it, and you're good to go.

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Certainly the FTC did not look kindly on that as well as class action plaintiff lawyers. The next round of advertising, you saw them sprinkling it on salads and probably chicken breast with the skin taken off and a whole different thing. So you're just always going to be viewed with skepticism unless you're making weight loss claims and indicate to be used in conjunction with a healthy diet and exercise program. Again, there are seven gut check claims causing permanent weight loss, losing more than three pounds per week for more than four weeks.

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The last category is substantial weight loss by wearing a product on the body or rubbing it into the skin. The FTC takes the position, they haven't seen the patch or the cream or something else that really works in losing weight. So be on the alert when you're making weight loss claims here, especially at the beginning. You're just going to be subject to greater scrutiny.

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Along those lines, cognitive health claims are also a category that receives a lot of attention from the FTC. Of course, claims suggesting treatment of Alzheimer's and other disorders, but anything having to do with cognitive function especially claims to increase memory focus or concentration are going to be looked at closer by the FTC. Again, as we talked about with COVID, really anything having to do with immunity is also going to be looked at with greater scrutiny.

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You're not prohibited from making immunity claims. I've seen some people say, well, we heard the FDA said, "You can't make immunity claims." FTC has sent a bunch of letters out over immunity claims. That's true, but it comes down to two things, you can't suggest a product will diagnose, treat, cure, or prevent a disease. So when you're making immunity claims, you can't say it's going to prevent colds. You can't say it's going to prevent COVID. You can't say it's going to do other things, and you have to have the science to back it up.

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So it's one thing if you just say your product is for immunity, but if you say it's to boost immunity or to improve immunity, you're going to have to have some pretty good science to support that your product will in fact help improve or boost immunity. The FTC and the FDA are both going to look closer at those claims during this time around COVID.

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All right. We're moving to number six, which is material connections. This has been an increased focus of attention from the FTC. Again, really important when you're making advertising, and this really goes a lot towards using customer reviews. So we're going to kind of talk about these together, material connections and consumer testimonials. You must disclose any material connection between a person advertising or talking about a product and the company itself. Material connection is anything of a personal, financial or business nature that might influence a person's opinion on that review. It doesn't mean that what that person is saying is not true. What the FTC has just said, a connection is something that a person looking to purchase a product should know about when they're making the determination of how much credibility to give that endorsement or review.

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So there's a variety of different ways in which this happens. You have the typical personal weight loss product where there's a picture of someone and they talk about all the weight that they lost. If that person is involved with the company, if that's a co-founder or an owner of the company, then they need to disclose that relationship to the company. It can be as simple as Justin Prochnow, CEO of such and such company when they're making that statement or that review is posted.

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Also it needs to be done fluidly with the advertising. A couple years ago, one of the FTC commissioners talked about a situation in which a well-known rapper had been talking about headphones and had tweeted out that he loved Lee's headphones and encouraged everyone to get some. There was a huge increase in sales. Then about four or five hours later, he actually tweeted out that he's got a partial ownership stake in that company. The FTC indicated ... They didn't take action in this situation, but they did indicate that that's not really an appropriate disclosure. That disclosure should have been done the first time it was announced. The reality is it might have even generated more sales because maybe people bought it, would buy more because he in fact is an owner. But it's something that the FTC says people should know when they're making that determination.

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About four or five years ago when the FTC updated their guidelines on endorsements and testimonials, the FTC took action against these two video gamers who were well known vloggers that talked about various games. They touted this new game and how great it was, and everyone should get it. They forgot to mention to everyone that they were actually part owners of that company. Again, doesn't mean what they're saying isn't true, doesn't mean that people might not buy it because of that, but the FTC says it's something people should know so that they can decide how much weight or credibility to give to that review.

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It's also really important when you're talking about consumer testimonials. I think we also have done a podcast talking about testimonials. So check out the archive again for that. It's important to understand that when a company uses a testimonial in its advertising, it is essentially adopting the content of that testimonial as content for the company. So put simply, a company should not be using any customer review or testimonial in which the person says something that the company would not be allowed to say

itself. Company can't say, "Well, it's not what we're saying. It's just the opinion of this customer." That's fine if that customer puts it on their own Facebook or Instagram feed or tweets it out.

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But once the company uses it, it's now the statement of the company. So the company must both substantiate it the same way, and it can't be making any claims that it wouldn't be mixed. So if I have Justin's Immune Support, and Rob tweets out something saying, "I love Justin's Immune Support. I never get colds and flu anymore." I can't use that review in my advertising because it's saying my product helps with colds and flu. And I wouldn't be allowed to do that if I was doing it myself. So I can't use a review to do that as well.

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Kind of along with those, before and after pictures. I usually use a slide that's got a before picture of Shrek and an after picture of the Hulk. Everyone can kind of imagine that. It's a claim. Even if you don't say anything, when you see before picture of Shrek and the after picture of the Hulk, and let's say it's on a protein powder or a workout product, there's a clear indication that this is implying you're going to get shredded from using this product. It might also mean that you're going to turn green, but you're certainly going to be shredded from doing it. So a lot of scrutiny from the FTC on before and after pictures. Clearly something that they pay a lot of attention to.

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Threw this one in specifically for the Affiliate Marketing Conference. But pictures of fake doctors, it's just something that the FTC often looks at when they're looking at those. If you have someone in a white lab coat, you need to disclose, and you can disclose it pretty easily. Just say, "Actor portraying doctor," even if it's in a video thing. You just need to disclose that's not a real doctor.

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Then finally, I'm going to wind up with "Made in the USA" claims. This has always been kind of an issue, but it's really come to the forefront in the last year and a half because of new regulations issued by the Federal Trade Commission. So for years, the FTC has had this guidance entitled, Complying With the Made in the USA Standard, posted on the FTC's website. Essentially, the FTC has regulated Made in the USA claims under that general proviso of all claims must be truthful, not misleading and substantiated. The general take was that made in the USA does not just mean that it was manufactured or put together in the USA. But the general takeaway is that it also means that all or virtually all of the parts of that product are also of US origin.

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So that means if you have a barbecue grill, one of the examples given by the FTC, it means that not only was that barbecue grill assembled and put together in the US, but all or virtually all of the parts are also from the USA. So the grill and the cover and all of that is also from the USA. If there's the ignition knob or one small part of the whole thing that's not from the USA, you can probably still make a Made in the USA claim without any qualification. In that guidance that FTC really doesn't address food and beverage, cosmetic products. So there was a lot of question as to what this really meant for food, beverage, supplement, cosmetic products. Of course our friends, the plaintiff lawyers had taken the position that if that gets extended out to foods and beverages, that means that not only is a food or a dietary supplement manufactured or produced in the USA, but all or virtually all of the ingredients are also from the USA.

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About four or five years ago, as we started seeing class action lawsuits over everything you can think of, they made their way into the Made in the USA realm. We started seeing actions against pet food, and condiments, and baby products, and dietary supplements claiming that a flag or just a straight Made in the USA claim was misleading if all or if not all or virtually all of the ingredients are from the USA.

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The FTC actually clarified this standard with a new regulation in the summer of 2021 and basically said, "You can only make a unqualified Made in the USA claim," exactly as we talked about. If not only was the product made in the USA, but all or virtually all of the ingredients are from the USA. While before that was guidance, it is now a specific regulation which makes it easier for the FTC to take action.

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It made it very clear that you must qualify claims if the origin of all the parts are not from the USA or you're unsure. So in the food, beverage, supplement, cosmetic industry, this really means you have to look at it carefully and say, not just that the manufacturing plant is in the USA. But what is the source of the ingredients? If they're not all from the US or you don't know, you really need to make some sort of qualified claim.

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So for example, if you said something like Made in the USA with US and international ingredients, Made in the USA with worldwide ingredients, manufactured in the USA with globally-sourced ingredients. Some of my clients get a little more creative "Made in the USA with awesome ingredients from around the world." Of course, in our era of class action litigation, you might find some plaintiff for who's going to sue you because they claim that you said it was awesome ingredients. And what is your basis for claiming that these ingredients are awesome?

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So you have to consider that as well, but you do have to make some sort of qualified claim. Now, you could also qualify it in terms of what process are you talking about. If you simply say "Bottled in the USA or Blended in the USA", you are likely going to avoid the general Made in the USA claim. The FDA has said that manufactured in the USA, produced in the USA, made in the USA are all considered to kind of be the same as made in the USA claims. So definitely an area to keep in mind. Simply just putting a flag on your product is also considered a implied made in the USA claim. So something to be aware of and especially on packaging, looking at to make sure that you are not putting yourself out there at risk for mostly class action plaintiff lawyers. I said I wasn't going to talk about them, and here I am ending the call with class action plaintiff lawyers but they seem to be ubiquitous these days, so it's hard to get out of here without saying something.

[\(37:14\)](#):

I'm going to stop today. That was a little bit longer than usual and me talking by myself. But some important topics to think about as you're doing advertising here in 2023. I appreciate you listening in. If you enjoyed it, please like it on your platform that you are listening to. Please tune in for our upcoming podcast in February. Thank you.