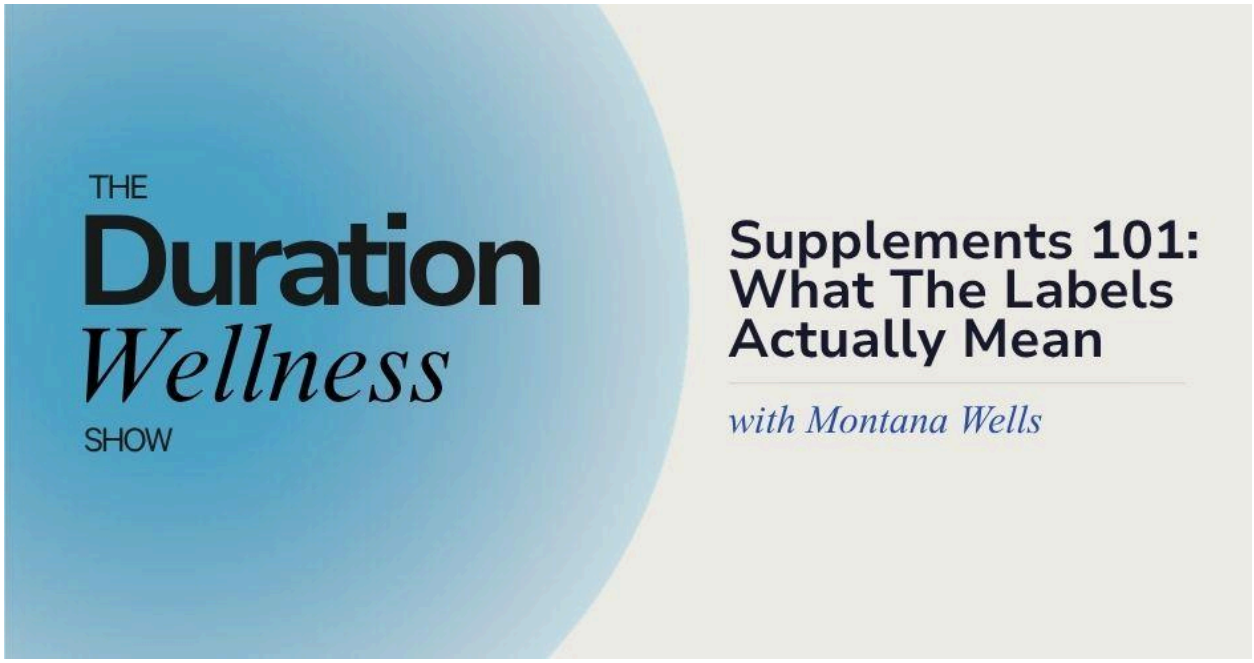

You grab a bottle of supplements, read the label, and see terms like "1,000 milligrams" and "third-party tested." But have you ever wondered what those labels actually mean? Here's the reality: Supplements aren't regulated like prescription drugs, so how do you know what you're taking is what it says you should be taking? We're pulling back the curtain on the supplement industry. Join us as we talk to Montana Wells, a biosystems engineer who is unpacking what goes on behind the scenes, detailing how supplements are engineered, how they're tested, what certifications guarantee, and what you, as a consumer, should be paying attention to. Stop guessing what's in your bottle—discover the truth behind identity, purity, strength, and composition in this essential guide to Supplements 101.

Watch the Episode here

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Supplements 101: What The Labels Actually Mean With Montana Wells

Introduction And Lack Of Regulation Compared To Prescription Drugs

Welcome to the show. We're here for another episode. We're going to talk all about supplements which am so excited for. We love supplements at Duration Wellness. We've developed our own supplement. Have you ever stopped and thought about what goes into supplements, what you're taking, not just the ingredients listed on the label, but how they're sourced, tested, and who's verifying what's promised is inside?

Here's a reality. Supplements aren't regulated like prescription drugs. They don't go through the same approval process. If that's the case, how do we know what we're taking is what it says that we should be taking? When a label says 1,000 milligrams, is it 1,000 milligrams? When it says third-party tested, tested for what exactly? We're unpacking what goes on behind the scenes, how supplements are engineered, how they're tested, what certifications guarantee, and what you, as a consumer, should be paying attention to.

I'm so excited to introduce our guest, Montana. He's a biosystems engineer. He is experienced in how supplements are made. He is bringing a practical perspective on the systems, processes, and manufacturing behind the products people use every day. He's also near and dear to my heart because he's my husband. This is Montana Wells. Welcome.

Thank you very much. Glad to be here. As you guys know, I am Annamarie's husband. My name is Montana Wells. A little bit about myself. I am the co-owner and one of the founders of Duration Wellness. It is a company focused on providing quality and scientifically informed supplements that support a healthy lifestyle. I'm originally from Oklahoma. I graduated from Oklahoma State with a degree in Biosystems Engineering.

My focus was on food and bioprocess. A lot of my professional background is in food and beverage manufacturing, and then specifically doing engineering roles or design roles. I would be designing food processing systems for different clients, selecting equipment, integrating them together, making sure they work correctly, and providing the quality food that the client is trying to produce to their specifications and within compliance with all FDA regulations on food safety and stuff.

A lot of it has been around maintaining, not only selecting and designing food-safe systems, but also working to get the quality and experience on that side of things. With Duration Wellness, I am serving as the lead person, vetting, as well as researching our strategic manufacturing partners, our testing partners, and diving into a lot of the regulatory requirements involved as a brand and firm that is looking to manufacture supplements for consumers to take and distribute.

There's a lot that goes into that part of the requirements, what the FDA looks for, and vetting out as firms release these products. It's fun, new, and a different part of my career that I've been doing. I'm familiar enough, especially on the food side and beverage side, with a lot of these requirements. This is a little different for me. It's been fun.

It's exciting. I'm excited about this episode, too, because in the supplements realm, a lot of people don't understand the labeling and what they should be looking for. This is going to be fun to talk about. Let's get into it. There's a lot of confusion and questions about how supplements are regulated. Also, a lot of people talk about how they're not as heavily regulated as pharmaceuticals. Why is that the case?

Historical Context Of Supplement Regulation And FDA Formation

They are not as regulated as pharmaceuticals. Depending on who you talk to, some people definitely think they should be. That's how it is. A lot of the history behind how supplements specifically have been regulated starts back at the turn of the century, back in the early 1900s and late 1800s. That's when the federal government started getting more involved in how our food was made. There were some food safety standards and regulations. It was the Pure Food Act in the early 1900s or 1908. That could be wrong. That was one of the first big pieces of legislation that formed the FDA and the Department of Human Services.

Back then, that's when it started to kick off. There were a lot of issues popping up, especially between the states and manufacturers. We had adulterated food and lots of poisoning. There were several cases that usually started all of this from the regulatory side. Even from that point on, the regulations and the laws that govern them end up getting stacked on top of each other. It's been amended over the last century or so. There's been a lot of different amendments. One of the bigger ones is the Food, Drug, and Cosmetics Act.

In the late 1930s, there were a bunch of issues around elixirs and different products causing mass poisonings. There was a case in the late '30s where, unfortunately, hundreds of people died because of poisoning issues. Before then, there was some effort to get more of this regulation in place. The FDA was pushing it even back then. That was the big catalyst that got it done. That set the beginning of regulating all food, drugs, cosmetics, and even started some medical devices.

It makes sense because back then, elixirs were all that people had. Penicillin came out in the late 1920s, but in terms of mass-produced, it wasn't until 1940. Around then, an elixir was all people had.

You bring up penicillin. There were even some concerns and issues with making sure penicillin was manufactured properly, because then, if your pharmaceutical wasn't manufactured safely or properly, you could take it. It's supposed to cure you. It kills you. There was a lot of push to do that. Over the century, it's been amended and modified in the regulations that started to develop. Title 21 in the Code of Federal Regulations is the big title right now that handles food, drugs, supplements, and different cosmetic medical devices.

Tweet: If a pharmaceutical isn't made safely, the very thing meant to heal you can end up harming—or even killing—you.

The Dietary Supplements Health And Education Act Of 1994

The Congress makes all the legislation. That's how the federal government puts it into action. They say, "This is what the law says. Here are the regulations that guide what you need to do." We have the current good manufacturing practices, the different requirements for food supplements, and the label laws that are built into them. Today's standards and regulations for supplements were based on 1994. That's when the last big push on the supplements of the Dietary Supplement Health and Education Act.

What that did was categorize supplements within the federal framework. Beforehand, it was weird between food and drugs. Even as early as the 1970s, there were some pushes from the FDA to start regulating specific supplements, specific minerals, or perhaps some hormones. They're out on the market based on potency alone or claims about what they do. Even back then, there were claims that the supplement would cure whatever disease or ailment.

The definition of a drug or pharmaceutical back then was typically a substance that would cure a disease, help diagnose, or affect. It's there, or it alters a person's former function. It may enhance you when you do something and when you eat. In your experience as a physician, when you see a pharmaceutical, you know that there are clear requirements for that pharmaceutical and testing what it says. I'm sure you can provide good examples of them.

The process is very stringent, and what you use it for in terms of FDA approval. Once a drug is FDA-approved, you can use it. There's something that we say is off-label. Ozempic would be a good category of your GLP-1, which are the weight loss drugs that everybody talks about now. They're marketed for weight loss.

It's what the FDA approved for now, but people started using them originally for diabetes. They found that they helped with weight loss. A lot of people originally used them off-label for weight loss. It started becoming popular. It started being studied more. The FDA approved it for that as well. There's what the FDA approved, and then there are off-label uses of medications as well.

The Distinction Between FDA-Approved Uses And Off-Label Uses Of Medication

Even if it's off-label, you still need it under the supervision of a physician. It was in the mid-century when the laws changed. A lot of these super-controlled substances did require a prescription from a physician or a medical practitioner. Even if you use it off-label, it's under the supervision of a practitioner, ideally. You can't just go to Walmart and get Ozempic. It's very controlled in supplements.

In the '70s, Congress passed a law to limit the FDA because the FDA was trying to say that, based on potencies or the amount of something, maybe you get 1,000% of your daily vitamin C. That may not have been exactly one, but there are some efforts to then bring that supplement under the category of a drug, especially if that person was saying that it's going to cure whatever ailment you have.

Congress indicated that they didn't want it to be that way. It was amended to say that just because you have a supplement or dietary supplement that was concentrated, you couldn't just regulate it. It was still more considered a food because some of these supplements go back and forth as far as whether they're a food or not. You can think of it like this. A supplement is a nutritional supplement.

It's supplementing your nutrition, but that's also when it gets a little tricky because there are brands that do claim, "You take this. It's going to make X, Y, and Z better." You still have to be very careful about that. You can, to an extent, under the regulation still claim a form or function improvement, but you still have to be careful. You cannot say it will cure your insomnia. That would be way too far.

It's going to cure this cancer, or you're going to become a genius.

Pharmaceuticals can't even say that. It has been studied and proven to treat something. You could say it's been treated for it because it's been approved by the FDA. Another big delineation between pharmaceuticals and supplements is before the supplement is released. You mentioned before that the

FDA goes through a rigorous process. Approval supplements don't have to. They're still regulated, but they can come to market without FDA approval. The FDA doesn't have to look at the formulation, look at the ingredients, and say, "Yes, this is fine."

It can come to market anyway, but the FDA does have the right to look at what you're doing and what you're putting on the label, and say, "You're being dishonest. This isn't there," or "You're not meeting the qualifications of it." Even in the regulations, there are still good manufacturing practices that are mandated. They're still testing requirements and specifications for supplements. It's not fast and loose. It's how it's set up. In some ways, especially from a documentation perspective, it's more intense than a standard food item.

Food is still regulated. Some foods are regulated and controlled more heavily than others, like meat and poultry. You got the FDA, but the USDA has a bunch of controls and inspections on that one, depending on the plant, but for ready-to-eat foods. There are different categories that may be more intense based on regulatory requirements or history. Overall, the quality control metrics and how you document everything started to get recategorized or redefined, back in the Dietary Supplements Act of 1994, which Congress passed. When they did that, that's when they inserted a lot more requirements as far as the different cGMPs and stuff like that.

The Importance And Meaning Of Third-Party Testing And Certifications

You mentioned a lot of testing right now because testing is very important. I feel like everybody always talks about third-party testing. That is always something that I tell patients they should look for in a body bottle when they're buying their supplements. What role do they play in? Should people be aware of them? Is it important? What do you think of third-party testing?

Current Good Manufacturing Practices (CGMPs) Explained

It's very good. It's a good indication if the person is following in the lines. Also, it's a good check for the brand itself, the firm that's doing it, or the manufacturer. There are a couple of different certifications or third-party testing. You might see something say, "cGMP-certified." cGMP means current good manufacturing practices. That's related to federal regulations. The federal law dictates that the manufacturing process has to meet a certain standard.

Tweet: Federal law requires the manufacturing process to meet certain standards.

I see that all the time. Honestly, I've never understood what it meant. If it's current good manufacturing practices, does that mean every supplement has to have that, even though they have a label? The United States is what I'm talking about.

Any manufacturer could get in trouble if they don't have that. The certification is voluntary. The minimum requirement is what's in the FDA statutes. It's title 21 and section 111. All supplements and the cGMPs are all in that one, if I remember correctly. You can check me on that. The law itself is the minimum. Theoretically, you could do it on your own, look at the laws, and know that your practices are good.

A lot of times, what a manufacturer may do or choose to do is go to a third party and say, "Will you look at my process, my facility, and how I'm doing business? Would you confirm that I'm following it based on what you understand about the federal regulations, as well as anything that you would need to be

associated with your third-party label?" Sometimes, the requirements for those labels may be beyond what the federal regulations require. It may be the base plus a little bit more.

There could be value, especially branding value, in that. When you see that on a bottle, that means that the supplement was made in a facility that has been certified, usually by a third party, to be compliant with the federal regulations on it. A lot of times, it's equipment that's designed for sanitary processing, so it can take food and not adulterate it. It's not made of cast iron. Cast iron is not allowed in that. It would not add any iron.

It wouldn't add iron. I just assumed cast iron would add iron.

That's not what you're worried about. It could potentially add it, but it could harbor microbial. It's very permeable. It can add rust to your product. You don't want that. Usually, standard steel or food-grade polymers, when you're doing that, it's got to be clean. On the manufacturing side of things and the equipment side of things, there's a whole bunch of set of rules that dictate what is considered to be the current good manufacturing practices as far as how they're manufactured.

Those change as new technology comes out. Maybe new features come out. That's a whole other show to go into itself. That says the equipment, the facility, and how they do business. CFGP is also covered. It's how you dress and groom yourself. The employees have to be to a certain hygienic standard when handling that.

If a supplement is third-party tested, they wouldn't necessarily then have to have the cGMP certification as well, but probably, if they're third-party tested, they would.

It depends. Think of the cGMP thing as how they made it. It does not touch on what the ingredients are. That is a different test. In the cGMP, it's a clean facility. You're not going to accidentally add some adulterant into the process at the facility. The other testing on the supplement ingredient side is a different certification.

That's testing the supplement itself.

That's the ingredient.

The cGMP is more of the manufacturing process, whereas third-party testing is testing of the actual supplement.

If you see it on a bottle, that's a good thing. Typically, if I were running a firm, I would not choose to manufacture my supplement or have it be manufactured in a facility that wasn't third-party certified. You can ask for the certifications. You can check that based on the certifying organization. There are several of them that do it. NSF has one. There are different third-party and international organizations that have recognition and stuff like that. There's a whole plethora of them.

For my clarification, this is always what I understood, why I thought third-party testing was so important, and why I would recommend it to patients when they're buying their supplements to make sure it's third-party tested. It's an outside source. It's then going to double-check that what is supposed to be in this bottle is in this bottle. It helps keep places honest because it's not the actual company itself that is doing it. It's another set of eyes. It's verifying this. Would you say that's a correct way to look at that?

I think so. That adds another level to it. That's also why you see some supplements that perhaps have the same active ingredient. It's the same citric acid, vitamin D, vitamin E, or whatever you're looking at. You're wondering, "What's the difference?" If it's third-party tested and they even have it listed, so they're complying with Clean Label, NSF, or any of those organization. That's probably a good indication that they're doing extra testing, except for the minimum, because the FDA does require you to test a minimum.

They have a whole set of specifications. Identity, purity, strength, and composition are basic requirements in the specification of a supplement. Each supplement by the FDA is required to have a spec that lists out identity. It is what it is. It is the entire product in the ingredient, because you do ingredient testing as they come into the facility. On the outside, you're supposed to do more testing on that part of it.

To go back to the third-party testing, because I want to make sure that I understand that, the third-party testing would be the product at the end, or not always?

You do both.

If something says third-party testing, though, does that mean for sure that it's tested at the end, or could it just have been third-party testing of what came in in the beginning, before you made the full supplement?

It would be hard to say without looking at it and that organization. Most of them are probably going to say that unless they have a lab that's doing all the relevant tests within their facility. You do the third-party testing because it's another set of eyes, especially if it's an independent organization. If you have an NGO or nonprofit, that's pretty good. There are also for-profit labs that do it. They're still reputable, especially if there's a whole other organization certification that certifies labs to make sure that they're compliant.

There's third-party testing. The International Standards Organization is the one that will certify a lab. They say that the lab is equipped correctly. They're using their stuff correctly. For any of the tests that they're doing for the different ingredients or different products, they have all the stuff there. It's good. If you're on the brand side of things when you're selecting things and you're selecting labs, it's very well recommended that you make sure they're listed or certified with ISO.

You can get their certifications and check them back to the organization to make sure that they're still compliant and in good standing before you pick them. Let's say it from a brand perspective. We got labs. We can test it. They may not show up on the label itself, but let's say you want to put a different label on it. I'll make one up. It's the Super Supplements of America brand. It's a third-party organization, an NGO, or a not-for-profit organization that cares about quality supplements. They have stringent regulations. You will make an application to them.

You'll show them how you're making your product, the different testing you do, all the ingredients that you have, your label, and everything. You give it to them. They'll look it through. They're like, "You're compliant." You might even submit some of the testing that you're doing. You're like, "This is good. All your labs check out." They'll say, "You go above and beyond. You meet our requirements to put our label on there because we've double-checked your work and said it's good." That's what that label on there means. They may be doing all their labs, but they give their work to somebody else to review.

The Role Of Product Specifications In Fda Compliance

They say, “I agree. This is good. This meets our standards.” Typically, it’s going to be above the base regulation or the minimum. You could put that label on there. There are marketing rules behind that, but it’s to show that you go above and beyond. I do want to make sure I was clear. I mentioned the product specification before. When the FDA is making regulations, usually, that’s one of the biggest things about most firms. I say firm brand. It’s a person in charge of making the ingredient and distributing it. You pick it up off the shelf at Walmart. That’s like that. That’s what I’m talking about.

The label there, the company that makes it, that’s it. A lot of times, they may partner with other manufacturers or a contract manufacturer. They may be the business that comes up with the formula. They come up with the specifications and the requirements, but they may contract a third-party manufacturer who then makes it for them. They give them the product. They sell it and distribute it wherever. It’s very confusing. The specification that I’m talking about that the firm will include all the ingredients. You also have to show how you confirm that the ingredients are what you say they are, so you do have to do testing. Depending on what you do, there are different tests for what it is.

Before that testing, to say what it is, that doesn’t necessarily have to be third-party tested. You’re verifying it.

Yes, and you want to be able to prove it. It’s probably wise. If you had your own lab that was compliant with FDA rules, and you got ISO certification on your internal lab. You could technically test it yourself and confirm it through a valid scientific means. The FDA may not say specifically, “For this product, you have to use this test.”

They give you an opening to do it, but you also have to prove that, “I use this scientific means to prove that the ingredient that I’m putting into my product is what I say it is. It does meet the other requirement. It’s not contaminated. It’s the potency. It’s the strength. It’s the amount that I say it is.” You’re not getting an ingredient that is supposed to be 100% vitamin C or whatever it is, but half of it is snake oil.

As what’s going around on Instagram, I always see, “Your supplements are just snake oil.”

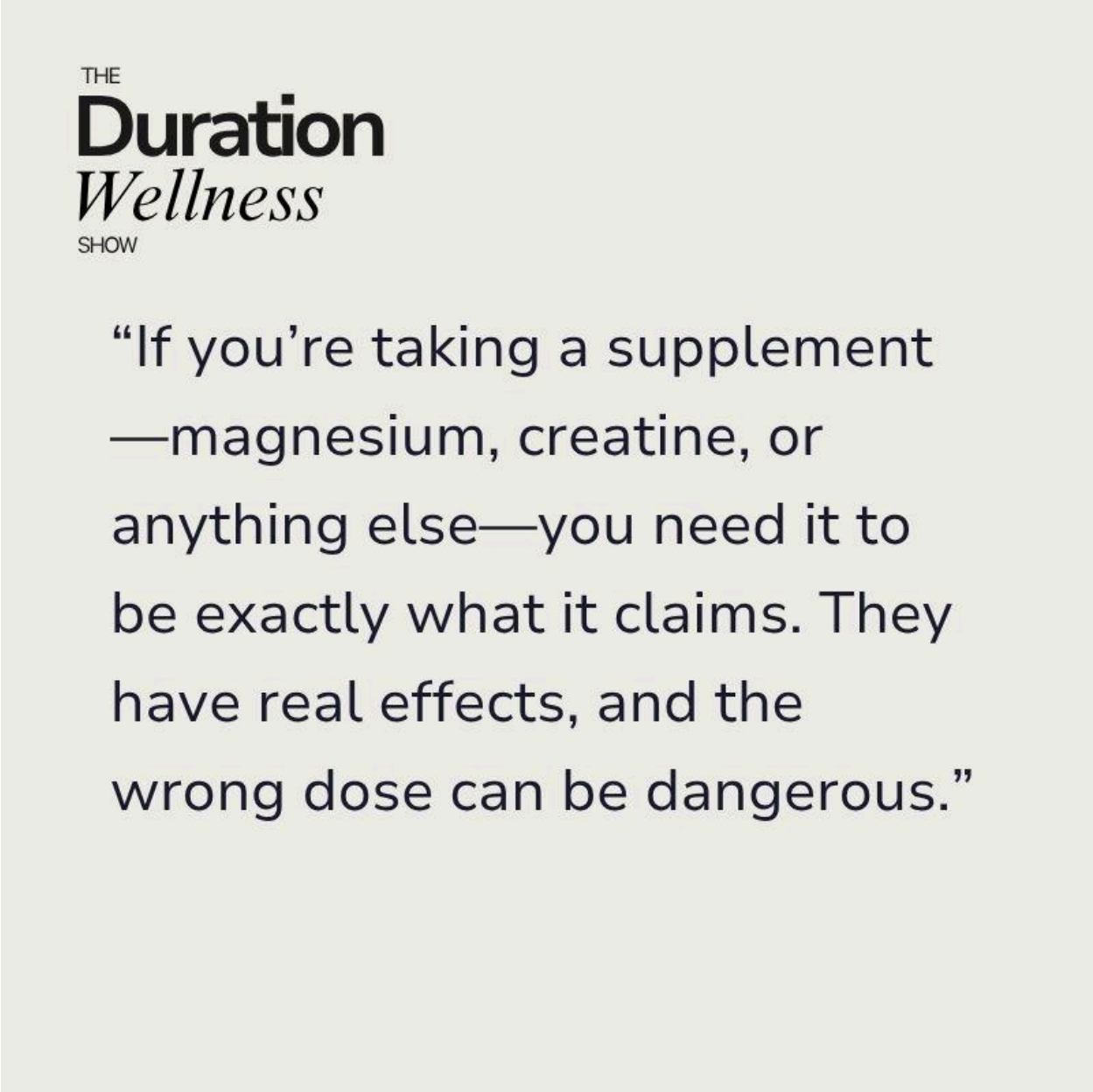
You have to show that it is there. If you don’t, the FDA will ding you. Usually, they give you the opportunity to correct your mistakes. They give you the opportunity to correct any errors that you made or any deficiencies in how you’re running your process or business. If your specification is deficient or you don’t have one, they will say, “You need to correct this.” If you don’t correct it, they can escalate. They can seize the product that you’re doing. They can mandate a recall. If it gets bad, they can take criminal action. From what I’ve researched and seen, a lot of times, they want you to just correct it and get in compliance before it escalates that badly.

To take an example, if there were a multivitamin, let’s say a bunch of B vitamins in it, like a B complex. If you’re third-party tested, would that technically have to be at the end of that production, what that pill is, that it would have all of those B vitamins. Not at the beginning when you were getting them into the facility? It wouldn’t have that, which counts as third-party testing. It would be at the end of the production of the pill.

Yes, that’s my understanding. You need to do it at the beginning and also at the end. You also want to do it at the beginning because before you do all this stuff, you want to make sure that it’s correct. At the

end, your final product is also what you're getting. Let's say all your ingredients are good, but in the manufacturing process, they messed up the formulation. What your final product is, if that's not what's on your label, and the ratios are completely off, then that would be non-compliance not only with your specification that you're supposed to provide, but also, it's just not. That's when they will get you. It's because what you have on your label needs to be what's in your product.

That makes sense. If you're taking magnesium, creatine, or whatever the supplement is, you want it to be what it says it is. That can be dangerous. Supplements still have effects. That's the whole reason you're taking them. You can overdose on supplements. You can overdose on medicines. They need to be the actual strength that they say they are.



Especially how the labels are and what goes into the labels, that's also where they're different from normal food. Food has a nutritional label, while supplements have a supplement label. They're very similar. They look similar in many ways when you first glance at them. When you go through the actual details and the information that's in the label, that's when they diverge.

Tweet: Food has a nutrition label; supplements have a supplement label. They may look alike at first glance, but the details reveal key differences.

For a food product, you're going to have the big macros, like the fats, the fiber, the carbohydrates, and the protein. You also have other major vitamins like vitamin C, vitamin D, iron, calcium, and all that stuff. That will show up in there, and your daily recommended one, which is also the daily recommended amounts of each vitamin or nutrient. It is also pulled from the FDA regulations that are listed there. That's what you base that on. Also, calories are the big one that's up there.

Supplements, though, are going to be formatted a little differently because you're going to go through all the active ingredients that you have in there. You need to specify exactly. Magnesium is a good one. You might have picked out a magnesium citrate. You have 1 gram of magnesium citrate, but you also notice on the side, in parentheses, it'll say the amount of elemental magnesium in that magnesium citrate.

It's a compound. There is an elemental aspect of it. That's what you want as a supplement. That's what counts. That elemental component of that magnesium citrate is the actual nutrient that you want and that your body wants. That number is in what's formulated to your daily value. You also lift both. You lift the total.

Ingredient Classification (Class 1 Vs. Class 2/Botanicals) And Accuracy Requirements

It is complicated because you could easily look at a bottle and say, "I'm getting 400 milligrams of magnesium," but then the elemental magnesium is maybe 50 milligrams or 130, way less. That's so complicated because you don't have that with pharmaceuticals. Your dose is your dose.

It's a baby aspirin. It's 81 milligrams, or 100 milligrams. That's very much where it's different. You go through ingredients A, B, and C. This is the amount. This is a nutritional amount. Even the type of vitamin C that you get will make a difference, if it's ascorbic acid. That's another good point. There are also different classifications of ingredients that you can put in a supplement, which then makes it a little more nuanced, too. There's class one and class two.

Class one is more fortified. They're fortified ingredients. They're fortified supplements. It's derived from man-made means. It's not from a plant. It's not from a botanical. It's mined. I'll pull up magnesium again. A lot of magnesium is either mined from a mineral, a specific rock, and then it's processed into the type of magnesium that you want, or it's pulled from the ocean, like sea salt or brine. You pull the magnesium from that source. It's processed, it's manufactured, and then you have that product. That's a class one iron.

You even see that with nutritional stuff. I won't say it's class one as far as if it's on a food grade. Class one or class two for supplements is what I'm talking about. Fortified bread has all those minerals and whatever. Wheat doesn't necessarily have that in the amounts that you're doing. You're adding it to

increase the nutritional value of a food product, while in supplements, it's the same situation. Class one ingredients require to have 100% of whatever you say is in your stuff.

It has to be very accurate.

If you say, "I have 100% of ascorbic acid, or I have 200 milligrams of ascorbic acid," It has to be 200 milligrams of that. It also has to maintain its shelf life over the period of time that you said. You also have to do shelf life testing. Let's say you get vitamin C from a botanical source. By botanical, I mean plants. It's grown. It's botanical. There is a little more wiggle room on that because, since it's biological, it's harder to get specific.

It's like if you're taking a chamomile pill.

They give you a bit more buffer. At least 80% of what you're listing on there has to be there if it's a botanical. It's a class two.

Probably a fair amount falls in that category.

There is. Part of it is that it's harder to scientifically get that accurate part. It's a little bit harder to do. They give you a little bit of wiggle room. The class one fortified stuff, you know exactly. That's from a manufactured source. It's very easy for us to scientifically confirm it is what it is. You're getting vitamin C from orange juice or whatever you're pulling it from. Not every orange is going to be identical. It is not going to produce the same amount.

Even seasonally, there are a lot of factors, like where it's grown, how it's grown, or the weather that year. Did it get enough water? Those will all impact the nutrients and the native botanical. From there on, it's harder. They give you a little bit more wiggle room on that one. It is supposed to still be very close. You also think about it. If it says 100 milligrams of whatever, but a class two ingredient, botanical ingredient, even if it's in plus or minus 80%, it's got to be there.

If you're below that, that would be a violation, or that would be something that you shouldn't do. I'm not saying that, necessarily, you don't know what a brand is doing. A lot of times, the third-party testing might help because they may say, "You've got to shoot high on your ingredient." If you go over what you're saying that you're putting in there, a lot of times, it's not as big of a deal. They care more that you have the minimum and what you say in there, it's got to be.

Tweet: Third-party testing can be a powerful reassurance. While the FDA oversees much of the industry, it can't catch everything—so an independent review means extra scrutiny and accountability.

If you had 101% of the magnesium that you listed in there, you're not going to get in trouble for that. Whatever consumer you're getting is getting a little extra, which is nice for them. It's maybe not as great for your bottom line. That's there. That's when there's some good nuance. Rose tips are botanicals. Another good thing is, when you come to the label, if you notice that it says it's from a botanical source, usually, you also have to state what part of the plant that you got it from, like rose tips, leaves, tea leaves, or extract.

It's where the actual source is from.

It's extracted from tea. The tea leaves are where you've got the tea leaf extract. "It's got the green tea in there, but I did it from the root." It has nothing to do with the actual nutrients that I was looking for.

That's also it. You're looking for this compound, or you see the botanical. It's like, "It's green tea extract." That has a very complex chemistry to it. This part of those chemistries is what you want. It's what's beneficial for you. At least that's what the claim is. They're also complex. It's also a part of the chemistries of it. It's hard to synthesize things without it getting a little thing. Hopefully, that didn't muddy the waters. It's a lot.

Honestly, it's reassuring that it's such an involved process.

You can look at the FDA website. It's public knowledge. There's a limit to what they say specifically. Usually, it's generic. If you look on there, you could see which firms got a violation. It's like, "In the last four months, five firms got violated because their standards were poor." That's usually what you see a lot of times. That's not to say that there isn't a nefarious actor out there that's selling stuff.

Back to the original thing that we were talking about, the third-party testing, that's why it could be a very good thing. It can be reassuring because the FDA regulates and is in charge of a lot of things. Sometimes, a firm may be manufacturing, processing, and doing stuff, and maybe it just doesn't get noticed by the FDA. If it has a third-party label on there, they have done a bunch of extra steps. Someone else has actively looked at the work.

That's not to say that the FDA isn't doing anything, because they are there. You think of how much is going on in the United States, how many supplements are sold, all the avenues that you can do online, retail, and all that stuff. It can be very reassuring. That doesn't mean that if a supplement doesn't have a third-party label on it, that it's trash or nefarious. That's not what that means.

It's just an extra step or an extra security.

All of these third-party labels are voluntary. When it comes to supplements, it's not there. You could still be doing a great job and following all the FDA regulations on your own, but it's harder to say.

Heavy Metal And Pesticide Testing Considerations

I read an article. Also, I feel like it's all over Instagram. People are making these claims that all of these supplements have an insane amount of heavy metals in them and that you're getting poisoned with heavy metals when you're taking supplements. Do you think every supplement needs to be heavy metal tested? Do you think that's true? What do you think of all of those?

With all of this stuff, it depends on what it is. It depends on what the ingredient is and where it's sourced. From a consumer, it is a lot harder to see. On some supplements, you can see the name brand of an ingredient. You could see magnesium glycinate, or maybe it's vitamin E. On the side of it, it's like, "This brand name is there." You go to that brand's website. You can look at all their different things and their certifications. Sometimes, it's nice to see a brand name on there because at least you can track one of the ingredients. It's still all the same rules, certifications, and all that stuff.

For magnesium, probably so, depending on where you're getting it from. If you're getting from the ground, if you're getting from whatever the source of that is, it's not a bad idea because maybe heavy metals are. They're in the ground where you're getting this ingredient from. You want to do it. If it's another product, like vitamin C, I would have to double-check to see what any recommendations are on the test. Let's say that whatever the ingredient is, it's very unlikely that it has that concern.

You may not want to decide to do that there. Maybe it doesn't make sense to test for pesticides on a specific ingredient because it's not sourced from anywhere where you would expect pesticides to get to. That doesn't necessarily mean that it can't. Sometimes, if a firm wants, they can go more in-depth and do a lot of different testing on a lot of different stuff to get there. The regs only require you to test for things that are reasonably expected to be contaminated from the source or how it can be contaminated.

It's not black and light. Sometimes, the regs are vague enough that it's up to you to figure it out. You've got to prove it scientifically or have some method. I can't even think of one off the top of my head, but there are some cases where there's not a good methodology to test. You've got to figure out a way around it. A lot of times, there are a lot of good sets.

The USP is another third-party non-profit. The United States Pharmacopeia was founded in the late 1800s. They were one of the first organizations in the United States to do drug testing. They were started by a group of physicians in DC in the late 1800s. You could go to their website and look up their exact history. I'm sure that would be accurate. They started that. It was voluntary until the '50s. Drug manufacturers can go to them and take their standards for all their testing of their different ingredients and processes because they have tons of standards that they've scientifically validated the test for whatever it is.

You can go there and get their list. "You're testing for this ingredient. Here are the recommended tests that you can do. Here's the science behind it. These are the requirements that you need to get it passed." That way, if the FDA were like, "What are you testing you could do?". If you pulled the USP and you're like, "I put it in there. This is what we did," they'd be like, "That's satisfactory." It's because they would recognize that.

For pharmaceuticals, in the '50s, and you can correct me, they changed it. It was changed by law that pharmacies have to be compliant with those tests for ingredients at that level. They've got different biologics. For supplements, it's still voluntary, though. It's not like you have to use their things, but they have it out there. That would be a way for you to pull something. They don't have tests for every single ingredient.

It's still in process because they also take public input. I'm nerding out on this stuff. They take public input. They develop it through different subject matter experts, different organizations, such as scientists. It's a lot of people. The public gets input on what should go into it, and then they release it. The industry usually is like, "Yes, that's a good example of it."

It's very helpful because a lot of people, myself included, apart from third-party testing, that was the only thing that I knew of in terms of recommending what you need for a supplement at baseline. I didn't know about half of the requirements that are there. Some of these supplements will have twenty million labels on them. You're like, "Is that helpful? Are they putting that on there just to put it on there?" I am curious. If on the label it says, "heavy metal tested." Does that mean that it was tested by a third party? Can the producer test it for the heavy metals, and does that suffice?

All that label, unless I saw it and it was like, "Third-party tested by this exact organization for heavy metals."

That could be done by just the supplier.

Maybe they could do a great job, especially if their labs got all the tools and it's compliant and certified. I would have to look into that a little deeper.

I was curious because it was something I was thinking about. You get third-party testing, but it doesn't necessarily mean that they're testing for heavy metals.

If they didn't do that, they would get in big trouble for it. That would be a violation of their thing. They'd probably get a letter from the FDA being like, "You've got to prove that you did it."

The idea is that they did it, but it's an extra step.

If they put it on there, I would probably have to dig into it a little more specifically on that one. I'm very confident that you cannot just blatantly lie on the label, or else that would be a violation. There may be some gray areas in there that could be better.

Tweet: You can't blatantly lie on the label. That would be a violation.

Heavy metal testing seems like something that depends on the supplement, when it's important, and when it's not. Same with pesticides, because that's something else that can be important depending on what the supplement is. If it's more of a botanical, that could be out where pesticides would be great.

If you see a botanical ingredient in there or something from a plant, probably a good idea. "That's nice to test for pesticides." Sometimes, even if it doesn't make sense, and they tested for it anyway, that's not a bad thing. There are cases when, sometimes, in shipment, your ingredients can get cross-contaminated. It's not even your fault or the ingredient manufacturer's fault. Something happens. Someone spilled Roundup on the shipping container.

There have been instances where there's cross-contamination in shipment, or maybe it gets to the facility. It's contaminated, but when it left the ingredients manufacturer, it was fine. You can do that. That's probably less true or rare. I would have to look into that more, but that could be something that can happen. That's definitely happened before. It may still be good to get that tested.

Sometimes, I've also heard that some people swear you have to get the creatine that's sourced from Germany versus the creatine that's from China.

It's up to you. If it's based in Germany, you can probably look it up. It's definitely under European manufacturing regulations. It's the control exports and everything there. Without looking at the requirements of how China regulates things, I'm not familiar. I'm a little bit more familiar with the European Union. I'm a little bit more familiar with their stuff because a lot of our regulations are, in many ways, similar.

A lot of times, Europe is much more stringent. They have a lot more stringent requirement. That may not be a bad idea. I'm not saying that if it's from China, India, or wherever, it's automatically bad. If it's from Germany, it's less likely that there is going to be an issue or there is going to be a miscontamination thing.

I've heard of it on Instagram. I haven't looked.

If you're not willing to look in deeply, it's probably a safer bet. I won't say that from other sources, it's absolutely true. I don't want to say that, but I do know that Europe, especially for their food and food regulations, supplement regulations, or just food in general, they have some of the most stringent and controlled standards in the world, especially in the market. It can go there, but the US and EU are among the highest in the world. That's safe to say.

The Step-By-Step Process Of Supplement Manufacturing

Going into the next section, we touched on it a little bit. How are supplements made?

It all starts with getting a formulation of what you want to make in a supplement. Let's say I have my own facility. I have built a facility. It is compliant with good manufacturing practices as outlined by the USDA, or maybe some other third-party testing that I have voluntarily subscribed to. I have a facility. I know what I want to make. I have the equipment and the systems in line ready to make it. I will first find a supplier of the different agreements that I want. That also includes anything that has to go into the supplement to make it.

There are sometimes additives that you have to put into certain ingredients to make them manufacturable. Sometimes, maybe a mineral or an iron, you might have to add a food-grade, food-safe additive to it to make it flow better, to put into a capsule, or to do whatever. There are sometimes things that you have to do because otherwise you can't get it into the form you want. All those are also regulated. There are rules about what food-grade stuff that you can and cannot do. You do have to list that on the label.

Let's say we're doing a capsule. We're doing a supplement. It's got a capsule. It's got three ingredients. I've sourced those ingredients. I figured them out and vetted them. They look and feel like they have the good certifications. I get it there. It comes to my facility. I'm going to test all the ingredients to triple-check.

You are required to make sure, by the FDA, that they are what they are, but you could believe whatever the ingredient company says. You could believe that if you want, but if it's wrong, it's your fault. That's also another thing. Earlier, I may have implied that the FDA makes you test that. They're not going to make you test it necessarily, but if it's wrong, you're on the hook for it. You've got to prove that it is what it is.

It is good.

It would behoove you. If it were my firm or my manufacturing facility, I would want to go ahead and test it to double-check it is what I say it is. Even in the food industry, you might still do some testing like that to make sure that they're not selling you a bad ingredient. Let's say you do that. We're a super reputable firm. We're going to do that. We do our testing. We get that in line. We start staging it. Let's say all these ingredients can be mixed.

We mix it in some piece of equipment that doesn't mix in the ratios we want. Maybe we can load it up into an unloader. It batches a specific amount of the ingredient we need for this product or this batch. We're making a 1,000-gallon batch or a 1,000-liter batch of this product. We dose in the exact requirements of it. As we're going through, the final ratio of that product has to be what's on our label. We're going to get it in. We're going to homogenize it well. We're going to make sure that the sample is all mixed together.

If you're mixing it and it doesn't mix well, there's a pocket of ingredient B in there. It's not going to distribute it. In your pills, there may be a whole lot that doesn't have any ingredient B, and then one lot that has only ingredient B. You're going to have to mix everything. As you're going through your manufacturing process and your specifications, you've got to show, "We're going to do this. It works well." As a manufacturer, you might do some individual testing in between to make sure that before it gets to the final filling or the final packaging, it's still good.

You're going to mix it. "This product doesn't require any extra steps. All of this has been done in a sanitary and hygienic environment, so we're not worried about contamination or adulteration of any kind. We're going to fill it into our pills or our capsules. They're made out of the food-grade vegan." There is cellulose or something like that. Also, on your label, you need to put what type of capsule you're using and what it's made out of. It's also true if you look at your things in there.

A lot of times, it's going to have those cellulose capsules. Sometimes, it might say vegan. You can get a certified vegan cellulose capsule, which may be good if it's vegan. That also might be a certification that you get. It's certified vegan, so all your ingredients are vegan. Your process doesn't use or add any animal products. A lot of times, those third parties will have the rules and make it magnesium ascorbic acid. You got in the capsule. Maybe you shake it out. You get a package, and then you put those capsules into a container.

Your specification also needs to list out, in that container, what it's made out of. That won't end up on the label, but you need to record that because the FDA may ask you. Maybe you put that hygienic, sanitary, sterile little cotton ball on the top of it, so it doesn't rattle around and break. You also need to make sure that it's good for your product and for the consumer experience, because you open a bottle, and all the pills are broken.

Also, you want to be in there because you want to protect the pills. You also want to make sure you maintain the integrity of the product for this shelf-life recommendation on there. You need to do a lot of manufacturing processes, typically. Manufacturers and brands will also have to do shelf-life testing to make sure it doesn't degrade over a period of time.

Maybe you seal poorly, and there's a lot of moisture in there. The moisture can not only degrade the supplement but potentially could a containment or adulterate it, too. You're going through your manufacturing. It's in a pill, and then that can get put in a box and shipped out, maybe direct-to-consumer, to a fulfillment center, or however we are going to do it.

I raised a question because for some of the omega pills and all those supplements, sometimes, they talk about them going rancid. Is the shelf-life testing at the end of production, or is it the end of production, and then also, in a month, they test it? How does that work?

I have to probably look a little bit more into it, but a lot of times when you're developing and confirming a product, you'll go ahead and do the testing there. Assuming that you're not changing manufacturing stuff, you may not have to do it as much, but every now and again, you may go ahead and do a repeat test. Maybe you changed an ingredient supplier. You just want to go ahead and make sure that it's not impacting it.

Usually, in the development of the product and when you're in the first couple of runs, you'll go ahead and do the shelf stability product testing. It may behoove you to do that multiple time throughout the

life of the brand or the product. It's not like there's a rule that's about, "Should do this test every six months?" There's not a rule like that in there, if that makes sense.

It's what the firm or the brand is, what their goals are, and what they feel comfortable with as far as making sure that they have a good product that is compliant with all applicable federal, local, and even state regulations. Sometimes, states might have specific requirements or regulations above what the feds require. California is pretty active in a lot of different food and beverage and supplement stuff, without doing any specifics.

You had already gone into this a little bit, but it'd be good to go over it again. You were saying specs, in terms of doing the specifications. What does that mean?

Key Specification Requirements (Identity, Purity, Strength, Composition, Adulteration)

In the federal regulations, it lists out that you are the brand, the manufacturer in charge of the product, or the person who owns the product. Let's say Duration Wellness. We have a product. It is our responsibility to make sure we have a specification that shows that we've looked through. We know what our product is composed of, what it's being made of, and the whole system.

If a regulator comes up and asks for it, we can hand it to them and say, “This is what we’re making. This is how we’re making it. This is what’s in it. This is how we proved that.” There are big things that go into it. There’s identity. Is it what you say it is? It’s the right thing. Is that a rose tip? Is it a rose tip extract? It is identifying the correct thing. Purity is clean. There’s nothing else in there. Is that true?

Strength is the amount in there. Do you have the amount that you say you have in there per unit? Is it 100% of this ingredient at 5 milligrams of this ingredient? Is that how much is in there? You have the composition of it. At the end of the product, does the composition of that thing that’s in the pill match what you have on the label, the ratios that you have it on, and the amounts that you have it on?

The final one is that it is not contaminated or adulterated with anything. Adulterated means there's nothing in there that's not supposed to be in there, or even on the life of the product. It's not getting ruined out of reason. You put it in a package. It sits there, and it's fine. It's not going to go rancid early or not, or there's no bacteria in there. That's not supposed to be in there or stuff like that. That's some big key parts of it.

The firm and the manufacturer are supposed to have that documented. The big things that firms get in trouble for are not having that clearly made, or maybe it's just not deficient. They're doing it, but they didn't write it down. That could be it. They're still making the product, as the product could all be fine, and all the testing's fine, but they didn't document it correctly.

The FDA is like, "You're in trouble." What happens if they ignore the FDA?

It can escalate. We mentioned a little bit before, but they could seize your product. They can shut down your manufacturing things if it goes more. There's some more legal stuff that gets involved. There can be fines and criminal penalties. I would have to double-check. I'm pretty confident about that. If you blatantly ignore them, it can escalate.

Usually, if the firm interacts with them and goes back and forth, a lot of times, it can get resolved before it gets bad, unless it's a severe public health concern or a threat to the public safety or health. You're putting something in there that you're absolutely not supposed to be putting in there. If it's an honest mistake, or maybe you just need to do a little better, then they might give you an opportunity to correct it. If it's something worse, they could get a much more severe reaction.

Differences Between Food Labels And Supplement Labels (Including Elemental Amounts)

There are labels on all these. We talked about this a little bit. If you're looking at a box of crackers, it's going to have all the nutrition. If you look at a supplement, it also has a lot of different things on it. Going over the differences in those labels and also just for supplements, it seems like you're supposed to be able to trust what is on there. I thought it was interesting even talking about how elemental magnesium is different than the magnesium milligrams that they list or the ingredient that they list.

There's magnesium citrate versus elemental magnesium.

Going over a little bit of when you're looking at this, what are you looking at?

What is in the label itself?

Yes.

We went over the food label. You don't have all the ingredients. You don't have the major nutrients. For the supplements label, it's much more geared toward the specific ingredients and also the amounts that you give. That's when it goes back and forth. It's not a pharmaceutical, but sometimes, especially how it's branded, it looks more like a pharmaceutical. That's the gray area where people get a little more critical of how brands market their products and stuff. I'm not saying it's bad or wrong, and it could very well be right.

A big thing is that you need to have the specific active ingredients that you're going to have in there, because a lot of times, for a supplement brand, it's usually claiming some form or function adjustment, "This is going to help your sleep. This is going to help your athletic performance. This is going to do X, Y, and Z." You have your active ingredients of what they do. You need to list those out and the quantities that you're supposed to have in there.

If it has a daily recommended value, a nutritional value like vitamin C, vitamin D, vitamin E, citric acid, zinc, or magnesium, which is a bit popular nowadays, there are specific daily recommended values that you're supposed to have in your diet. That might be the percentage. Sometimes, the percentage is more than your daily recommended, like 1,000% of vitamin E or something like that, because that means that it is more than what your daily recommended amount is for. We'll have those there and the elementals. If the compound itself has the ingredient or the element in there, but maybe it's not all of it, that's where the magnesium citrate comes in.

Sometimes, you can get pure forms of ascorbic acid. It said that matches. You have the daily recommended values of those that have to be listed. You also get that on nutritional labels, but again, it's more like 30% of your daily protein or your added sugar. That's on nutrition, but this one is for that ingredient or that target nutrient that you're doing. It's much more specific.

Any other ingredients that are in there that are not active, you will also list them at the bottom. That's where your capsule is, and maybe any other preservative or ingredients that you might have in there to make sure that it's shelf-stable. Maybe some of the stuff might degrade over time if you don't put it in oil or something like that. You've got your fish oil. It's got the Omega-3s, but it's suspended in some oil or whatever it is. That's not an active ingredient. That might still be on there, but you don't have to list that.

It would be at the bottom.

It wouldn't have to be in that part of it. What's another good point to make? We mentioned before, the botanicals. Usually, if it's from a specific part of the plant, you have to list what that specific part is. It's from tea leaves. It's from elderberries, the berry extract, or extract of the berries themselves. It's the elderberry root. You've got to get specific on where you're extracting it from. Sometimes, they'll say that thing, and then in parentheses, and maybe from its roots or from its leaves.

There are also the dosing requirements. On nutritional labels, they usually do common servings. Five servings are one patty, or one serving per patty. Usually, supplements get much more specific. This supplement panel on the label is three capsules, or it's one 5-gram scoop. A 5-gram scoop of this is this. That's the serving. That's when it gets closer to how pharmaceuticals are, because usually, it's like, "One tablet per day." That's where it gets in. That's another thing. It's usually very specific dosing requirements. You might get a bottle of 120 pills, but the serving size is two pills. Maybe it's one, or maybe it's three. That is how you will have to adjust it from there.

Also, the supplements are going to have a disclaimer saying, "The FDA has not evaluated this to treat." It will have something on there saying, "This is not intended to treat, cure, or prevent," because if you're going to make those claims, it sounds much more like a pharmaceutical or something more like a drug. You've got to be very careful. You can make a form or function. It's going to support sleep. It's going to support recovery, or it's going to support brain health or cognitive function. That's a clear thing that you can make on that.

You can also make some claims on that for food, like part of a balanced breakfast, or milk helps grow strong bones. You can make those form-function claims, but you're not supposed to put, "It's going to cure your Lyme disease." The FDA for a drug is going to review something before it goes to market and confirm through its regulations and standards that it does what it says it does. A supplement could go to market before that, and then the FDA usually is going to get it for if it is what you say it is, then it's okay.

Even those third-party labels that we mentioned before, a lot of times, they're going to confirm that the ingredients in the product are what they say they are, they're not contaminated, and they're free of heavy metals, pesticides, or whatever. A lot of them do not test for efficacy. They're not going to test to make sure that it does what the claim says it's going to do. If you get a third-party test like the Super Supplements of America third-party testing, they're not going to confirm if it helps you recover from exercise.

Even pharmaceuticals, to a degree, have proof. They have evidence that it does support. That's not to say that some supplements can't. There is no evidence out there that these supplements support that stuff, but those claims are very different from what they are. Those tests pretty much make sure that it is what you say it is and it's safe. It's not going to test to see if it does what it's implying that it's supposed to do. Probably the biggest thing when you hear people critiquing supplements and stuff like that is the marketing, the branding.

That's also why it's important to review the branding and the marketing from a consumer standpoint if you can. It's hard to say, but that's something that you can take into mind. If it's promising the world, as a consumer, I would be a little hesitant about trying to look forward to it. Maybe look for a brand that's more honest. There are some things out there that even you could test. There's very good research and literature that says that zinc is supportive of your immune system. There's a lot of research out there that does support that.

Tweet: It's important to evaluate branding and marketing from a consumer's perspective. Even if it's not always easy, it's something worth keeping in mind.

There's creatine with brain health.

There is stuff out there that does support. That's probably fine. If it's this super rare root from the Amazon that is going to help cure eczema or something like that, back up. Especially if it says cure, that's usually when some of the regulators will come and be like, "You can't say that." The phrasing of it is very important.

That makes sense. This is cool. That explained a lot. I found it very interesting. Anything that you think we missed that we should talk about?

No, other than it would spin off into an entirely different show. Maybe we'll do that for sections 2, 3, and 4. I'm glad that you're patient with me and all this because I felt like going down rabbit holes.

It's great. I learned a lot. Hopefully, everybody here did, too. As always, this is not intended for medical advice. This is for educational purposes only. I had a great time on this episode. It was so fun. Hopefully, you guys did, too.

I'm glad to be here.

Thanks.

Important Links

- Montana Wells on LinkedIn
- FDA
- NSF
- Clean Label Project
- US Pharmacopeia (USP)

About Montana Wells

Montana Wells is originally from Oklahoma and graduated from Oklahoma State University with a degree in Biosystems Engineering, with an emphasis in Food and Bioprocess.

Professionally, Montana has built his career in manufacturing process design and engineering within the engineering and construction industry. His work has focused primarily on process systems design, equipment integration, and facility support for food and beverage manufacturing environments.

At Duration Wellness, Montana leads the company's manufacturing and quality partnership efforts. His role includes vetting strategic manufacturing partners, supporting product development, coordinating third-party testing relationships, and helping ensure that Duration Wellness products are developed with a strong focus on FDA regulatory compliance, quality standards, and applicable third-party certification programs.